IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

SHOSHONE-BANNOCK TRIBES,

Plaintiff,

v.

PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY; CEPHALON, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; JANSSEN PHARMACEUTICALS, INC.; JOHNSON & JOHNSON; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS INC.; ALLERGAN PLC, f/k/a ACTAVIS PLC; WATSON PHARMACEUTICALS, INC.; WATSON LABORATORIES, INC.; ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC.; ACTAVIS LLC; INSYS THERAPEUTICS, INC.; MALLINCKRODT PLC; MALLINCKRODT LLC; MCKESSON CORP.; CARDINAL HEALTH, INC.; AMERISOURCEBERGEN CORP.; CVS HEALTH CORPORATION; WALGREENS BOOTS ALLIANCE, INC. A/K/A WALGREEN CO.; WALMART, INC.; THE KROGER CO.; RITE AID OF MARYLAND and HEALTH MART SYSTEMS, INC.,

Defendants.

MDL Case No. 1:17-md-2804

Hon. Dan A. Polster

Case No. _____

COMPLAINT

JURY TRIAL DEMANDED

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I. INTRODUCTION

1. An epidemic of prescription opioid abuse is devastating the United States. Indian Country has been particularly hard hit, causing Plaintiff Shoshone-Bannock Tribes (hereinafter referred to interchangeably as "Plaintiff" or the "Tribe") to suffer substantial loss of resources, economic damages, and damages to the health and welfare of its members.

2. Plaintiff brings this action in its own proprietary capacity and under its *parens patriae* authority in the public interest to protect the health, safety, and welfare of all members of the Tribe.

3. Opioid analgesics are a dangerous, highly addictive and often lethal class of natural, synthetic, and semi-synthetic painkillers. In total, from 1999 to 2016, more than 350,000 people died from an overdose involving any opioid, including prescription and illicit opioids such as heroin. Well over half of those deaths—over 200,000 people—involved legal opioids prescribed by doctors to treat pain. These legal opioids include brand-name prescription medications like OxyContin, Opana, Subsys, Fentora, and Duragesic, as well as generics like oxycodone, methadone, and fentanyl. Opioid analgesics are widely diverted and improperly used, and the widespread abuse of opioids has resulted in a national epidemic of opioid overdose deaths and addictions.[1] The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[2]

[1] *See* Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 N. Eng. J. Med. 1253 (2016).

[2] *See* Robert M. Califf et al., *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (2016).

4. This epidemic has been building for years. The conditions for its creation and acceleration were intentionally brought about by Defendants, who made billions of dollars from the epidemic.

5. The effects of the opioid crisis have been exacerbated by Defendants' efforts to conceal or minimize the risks of—and to circumvent or ignore safeguards against—opioid abuse.

6. The Tribe has seen substantial increases in child welfare and social services costs associated with opioid addictions. Its health services have been significantly impacted and education and addiction therapy costs have substantially increased.

7. These costs could have been—and should have been—prevented by the opioid industry. The prescription drug industry is required by statute and regulation to secure and monitor opioids at every step of the stream of commerce, thereby protecting opioids from theft, misuse, and diversion. The industry is also supposed to implement processes to alert it to "red flags" that stop suspicious or unusual orders by pharmacies, doctors, clinics, or patients.

8. Instead of acting with reasonable care and in compliance with their legal duties, Defendants intentionally flooded the market with opioids and pocketed billions of dollars in the process.

9. Defendants also flooded the market with false statements designed to persuade both doctors and patients that prescription opioids posed a low risk of addiction. Those claims were false.[3]

[3] *See* Vivek H. Murthy, *Letter from the Surgeon General* (August 2016), available at http://turnthetiderx.org/ (last accessed December 18, 2017).

10. Defendants' actions directly and foreseeably caused damages to the Tribe, including, but not limited to, the costs of (a) medical and therapeutic care, and other treatment costs for patients suffering from opioid addiction, overdose, or death; (b) opioid prescriptions for chronic pain paid directly through the Tribe's health care system, dispensed as a direct result of Defendants' widespread, pervasive and misleading opioid campaign; (c) counseling, treatment and rehabilitation services; (d) treatment of infants born with opioid-related medical conditions; (e) welfare and foster care for children whose parents suffer from opioid-related disability or incapacitation, including costs of related legal proceedings; (f) law enforcement and public safety connected to the opioid epidemic within the Tribe's community, as well as the surrounding communities; (g) increased burden on the Tribe's judicial system; (h) re-education of doctors and patients about the appropriate use of opioids; and (i) extensive clean-up of public parks, spaces, and facilities.

11. Defendants' actions have not only caused significant costs, but have also created a palpable climate of fear, distress, dysfunction and chaos among tribal residents where opioid diversion, abuse, and addiction are prevalent and where diverted opioids tend to be used frequently.

12. Plaintiff has also suffered substantial damages in the form of lost casino revenue, lost productivity of tribal members, lost economic activity, lost reputation and good will, and the lost opportunity for growth and self-determination. These damages have been suffered and continue to be suffered directly by the Tribe.

13. Plaintiff also seeks the means to abate the epidemic created by Defendants' wrongful and/or unlawful conduct.

II. THE PARTIES

A. Plaintiff

14. Plaintiff Shoshone-Bannock Tribes is a federally recognized sovereign Indian nation. The Shoshone-Bannock Tribes are comprised of the eastern and western bands of the Northern Shoshone and the Bannock, or Northern Paiute, bands. The Fort Hall Reservation was reserved for the Shoshones and Bannocks when the tribes entered into the 1868 Fort Bridger Treaty. The Fort Hall Reservation is located in the eastern Snake River Plain of southeastern Idaho. The reservation originally contained 1.8 million acres, but was subsequently reduced through legislation and the allotment process to its present size **o**f approximately 544,000 acres. The reservation runs through four counties in Idaho: Bingham, Power, Bannock and Caribou.

15. The Tribe is organized under a Constitution and Bylaws ratified by members of the Tribe and approved by the United States Department of the Interior ("Interior") in 1937.

16. The Tribe has inherent sovereign authority over its members and its territory, which is set aside for the exclusive use and occupancy of the Tribe and its members as a permenant homeland.

17. The Tribe has approximately 6,000 members with a significant number of Tribal members residing on the Reservation. The Tribe is confronted with substantial social challenges associated with unemployment and poverty, including, without limitation, diminished life expectancy, poor health indicators, low high school graduation rates, crime, and drug use.

18. The Tribe has inherent sovereign authority to make its own laws. State law does not generally apply to Tribal activity within the Reservation. Certain

enumerated governmental powers are vested in a Tribal Council. The Tribal Council has seven members, with members elected by enrolled members of the Tribe.

19. The Tribal Council oversees the Tribe's administration of services to its members, including natural resource management (both within and outside the Reservation), a court system, police and fire protection, water and sewer services, a housing authority and social services. The Tribe operates a health clinic, which provides medical, dental, vision and pharmacy services to the entire reservation community. The Tribe also operates a gaming and hospitality business with multiple casino locations. Dedicated to improving the quality of life of Tribal members, the Tribe engages in various activities in the fields of health care, housing, education, agriculture, economic development and cultural development in order to achieve that goal.

20. The Tribe has inherent sovereignty over unlawful conduct that takes place on, or has a direct impact on, land within the Reservation. Federal law recognizes the Tribe's authority over Indians within its territory, specifically the authority to promote the autonomy and the health and welfare of the Tribe. Defendants engaged in activities and conduct that takes place on or has a direct impact on land that constitutes Indian Country for the Tribe. The distribution and diversion of opioids into Idaho and onto the Tribe's lands and surrounding areas, created the foreseeable opioid crisis and opioid public nuisance for which the Tribe here seeks relief.

21. The Tribe has standing to recover damages incurred as a result of Defendants' actions and omissions. The Tribe has standing to bring actions including, *inter alia*, standing to bring claims under the federal RICO statutes, pursuant to 18 U.S.C.

§§ 1961(3) and 1964 and standing to bring its public nuisance claims asserted under federal common law.

22. Members of the Tribe affected by the opioid crisis described in this Complaint live on the Tribally owned lands, as well as throughout Idaho and the United States.

B. Manufacturer Defendants

23. The Manufacturer Defendants are defined below. At all relevant times, the Manufacturer Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted, and purported to warn or purported to inform prescribers and users about the benefits and risks associated with the use of prescription opioid drugs. The Manufacturer Defendants, at all times, have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders.

24. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware. PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut, and THE PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business in Stamford, Connecticut (Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company are referred to collectively as "Purdue").

25. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER,[4] and Targiniq ER

[4] Long-acting or extended release (ER or ER/LA) opioids are designed to be taken once or twice daily. Short-acting opioids, also known as immediate release (IR) opioids, last for approximately 4-6 hours.

in the U.S., including in Idaho. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from its 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers). Purdue has manufactured and distributed substantial amounts of prescription opioids that have been and continue to be sold nationwide, including in Idaho, where the Tribe is located.

26. CEPHALON, INC. is a Delaware corporation with its principal place in Frazer, Pennsylvania. TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a wholly owned subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of business in Pennsylvania. Teva USA acquired Cephalon, Inc. in October 2011.

27. Cephalon, Inc. manufactures, promotes, sells and distributes opioids such as Actiq and Fentora in the U.S., including in Idaho. The FDA approved Actiq and Fentora only for the management of breakthrough cancer pain in patients who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay $425 million.

28. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out

Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon-branded products through its "specialty medicines" division. The FDA approved prescribing information and medication guide, which is distributed with Cephalon opioids marketed and sold in Idaho, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. Teva Ltd. has directed Cephalon, Inc. to disclose that it is a wholly owned subsidiary of Teva Ltd. on prescription savings cards distributed in Idaho, indicating Teva Ltd. would be responsible for covering certain co-pay costs.

29. All of Cephalon's promotional websites, including those for Actiq and Fentora, prominently display Teva Ltd.'s logo. Teva Ltd.'s financial reports list Cephalon's and Teva's USA's sales as its own, and its year-end report for 2012 – the year immediately following the Cephalon acquisition – attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon's specialty sales." Through interrelated operations like these, Teva Ltd. operates in Idaho and the rest of the United States through its subsidiaries Cephalon and Teva USA. The United States is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies' business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. (Teva Pharmaceuticals Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to collectively as "Teva" or "Cephalon"). Teva has manufactured and distributed

substantial amounts of prescription opioids that have been and continue to be sold nationwide, including in Idaho, where the Tribe is located.

30. Teva also manufactures, markets, sells and distributes generic opioid pharmaceutical products, both prior to Teva Ltd.'s 2011 acquisition of Cephalon and continuing to the present, including a generic form of Oxycontin from 2005 to 2009 nationally, including in Idaho. Teva Ltd. acquired numerous generic manufacturers over the years that manufactured, marketed, sold and distributed generic opioid products (including a generic form of Actiq starting in 2006), and continues to sell many of those products to this day through its U.S. subsidiary Teva Pharmaceuticals USA, Inc. Teva Ltd.'s acquisitions include Barr Pharmaceuticals in 2008 and the Actavis generic pharmaceutical business in 2016, which included the acquisition of defendants Watson Laboratories, Inc., Actavis Pharma, Inc. f/k/a Watson Pharma, Inc., and Actavis LLC.

31. In 2016, Teva Ltd. acquired ANDA, Inc. from Allergan, plc for $500 million. At the time of the acquisition, Anda, Inc. was the fourth largest distributor of generic pharmaceuticals in the U.S. according to Teva's August 3, 2016 press release. Plaintiff is informed and believes that ANDA, Inc. distributed generic opioid products for both Allergan, plc and for Teva in the U.S., including in Idaho, and was wholly controlled by Allergan, plc and, from 2016 after its sale to the present, Teva Ltd.

32. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of JOHNSON & JOHNSON ("J&J"), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as Janssen Pharmaceuticals, Inc.,

is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA, INC., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. (Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and J&J are referred to collectively as "Janssen"). Upon information and belief, J&J controls the sale and development of Janssen Pharmaceutical's products and corresponds with the FDA regarding Janssen's products.

33. Janssen manufactures, promotes, sells, and distributes drugs in the U.S., including in Idaho, including the opioid Duragesic (fentanyl). Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014. Janssen has manufactured and distributed substantial amounts of prescription opioids that have been and continue to be sold nationwide, including in Oregon, where the Tribe is located. Upon information and believe, Johnson & Johnson through its indirect wholly owned subsidiary Patriot Pharmaceuticals LLC sells and distributes authorized generic opioid products nationwide, including in Idaho.

34. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are referred to collectively as "Endo").

35. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the U.S., including in

Idaho, where the Tribe is located. Endo also manufactures and sells generic opioids, both directly and through its subsidiary, Qualitest Pharmaceuticals, Inc., including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the U.S., including in Idaho, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

36. ALLERGAN PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. ACTAVIS PLC acquired Allergan plc in March 2015. Before that, WATSON PHARMACEUTICALS, INC. acquired Actavis, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then Actavis plc in October 2013.

37. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Corona, California. ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey, and was formerly known as WATSON PHARMA, INC. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants was owned by Allergan plc prior to their acquisition by Teva Ltd. in 2016, which used them to market and sell its drugs in the United States. Watson Laboratories, Inc., Actavis Pharma, Inc. and Actavis LLC are referred to collectively as the "Actavis Generic entities." Upon information and belief, Allergan plc exercised

control over these marketing and sales efforts and profited from the sale of Allergan/Actavis products ultimately inured to its benefit.

38. Allergan plc, Actavis, Inc., and Watson Pharmaceuticals, Inc., and Actavis LLC, Actavis Pharma, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. (the Actavis Generic entities) prior to their acquisition by Teva Ltd. in 2016, are referred to collectively as "Actavis").

39. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana as well as other generic opioid products, in the U.S., including in Idaho where the Tribe is located.

40. Defendant INSYS THERAPEUTICS, INC., is a Delaware corporation with its principal place of business located in Chandler, Arizona.

41. Insys manufacturers, promotes, sells, and distributes opioids. Insys' principal source of revenue is Subsys, a Schedule II transmucosal immediate-release formulation of fentanyl in the U.S., including in Idaho where the Tribe is located. Subsys was indicated by the FDA for the treatment of breakthrough cancer pain that other opioids could not eliminate.

42. In May 2018, an Insys sales representative admitted to taking part in a scheme to bribe physicians with purported speaking fees for marketing and education events in exchange for them prescribing Subsys for off-label uses.

43. Insys' founder and several other former Insys executives were recently indicted by federal prosecutors on racketeering charges, alleging that these individuals

approved and fostered fraudulent behavior against insurance companies and also conspired to bribe practitioners in various states.

44. MALLINCKRODT, PLC is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. MALLINCKRODT, LLC, is a limited liability company organized and existing under the laws of the State of Delaware. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, plc. Mallinckrodt, plc and Mallinckrodt, LLC are collectively referred to as "Mallinckrodt."

45. Mallinckrodt manufactures, markets, and sells drugs in the United States including generic opioid products including oxycodone, of which it is one of the largest manufacturers. In July 2017, Mallinckrodt agreed to pay $35 million to settle allegations brought by the Department of Justice that it failed to detect and notify the DEA of suspicious orders of controlled substances. Mallinckrodt has manufactured and distributed substantial amounts of prescription opioids that have been and continue to be sold nationwide, including in Idaho, where the Tribe is located.

46. Collectively, Purdue, Cephalon, Janssen, Endo, Teva, Allergan, Insys, and Mallinckrodt are the "Manufacturer Defendants."[5]

C. Distributor Defendants

47. CARDINAL HEALTH, INC. ("Cardinal") is a publicly traded company incorporated under the laws of Ohio and with a principal place of business in Ohio.

[5] Together, these entities are also sometimes referred to as "RICO Marketing Defendants."

48. Cardinal distributes prescription opioids to providers and retailers, including in Idaho where the Tribe is located. Cardinal is authorized to conduct business in Idaho.

49. AMERISOURCEBERGEN CORPORATION ("AmerisourceBergen") is a publicly traded company incorporated under the laws of Delaware and with a principal place of business in Pennsylvania.

50. AmerisourceBergen distributes substantial amounts of prescription opioids to providers and retailers nationwide, including in Idaho where the Tribe is located. AmerisourceBergen is authorized to conduct business in Idaho.

51. MCKESSON CORPORATION ("McKesson") is a publicly traded company incorporated under the laws of Delaware and with a principal place of business in San Francisco, California.

52. McKesson distributes prescription opioids to providers and retailers nationwide, including in Idaho where the Tribe is located. McKesson is authorized to conduct business in Idaho.

53. The data which reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in the DEA's confidential ARCOS database. *See Madel v. U.S. D.O.J.*, 784 F.3d 448, 451 (8th Cir. 2015). Neither the DEA nor the wholesale distributors will voluntarily disclose the data necessary to identify with specificity the transactions which will form the evidentiary basis for the claims asserted herein. *See id.* at 452-53.

54. Collectively, AmerisourceBergen, Cardinal, and McKesson dominate 85% of the market share for the distribution of prescription opioids. The "Big 3" are

Fortune 500 corporations listed on the New York Stock Exchange whose principal business is the nationwide wholesale distribution of prescription drugs. *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 37 (D.D.C. 1998) (describing Cardinal, McKesson, and AmerisourceBergen predecessors). Each has been investigated and/or fined by the DEA for the failure to report suspicious orders. The Tribe has reason to believe each has engaged in unlawful conduct which resulted in the diversion of prescription opioids into the Tribe's community. The Tribe names each of the "Big 3" herein as defendants and places the industry on notice that the Tribe is acting to abate the public nuisance plaguing its community. The Tribe will request expedited discovery pursuant to Rule 26(d) of the Federal Rules of Civil Procedure to secure the data necessary to reveal and/or confirm the identities of the wholesale distributors, including data from the ARCOS database.

55. Defendant CVS HEALTH CORPORATION ("CVS") is a Delaware corporation with its principal place of business in Rhode Island. During all relevant times, CVS has sold and continues to sell prescription opioids at locations in Idaho and in the communities adjacent to the Reservation. CVS is authorized to conduct business in Idaho.

56. Defendant WALGREENS BOOTS ALLIANCE, INC., also known as Walgreen Co. ("Walgreens") is a Delaware corporation with its principal place of business in Illinois. At all relevant times, Walgreens has sold and continues to sell prescription opioids at locations in and around Idaho and in the communities adjacent to the Reservation. Walgreens is authorized to conduct business in Idaho.

57. Defendant WALMART, INC. ("Walmart") is a Delaware corporation with its principal place of business in Arkansas. At all relevant times, Walmart has sold

and continues to sell prescription opioids at locations in and around Idaho and in the communities adjacent to the Reservation. Walmart is authorized to conduct business in Idaho.

58. Defendant THE KROGER CO. ('Kroger") is an Ohio corporation with its principal place of business in Ohio. At all relevant times, Kroger has sold and continues to sell prescription opioids at locations in and around Idaho and in the communities adjacent to the Reservation. Kroger is authorized to conduct business in Idaho.

59. Defendant RITE AID OF MARYLAND ("Rite Aid") is a Delaware corporation with its principle place of business in Camp Hill, Pennsylvania. During all relevant times, Rite Aid has sold and continues to sell prescription opioids at locations in and around Idaho and in the communities adjacent to the Reservation. Rite Aid is authorized to conduct business in Idaho.

60. Defendant HEALTH MART SYSTEMS, INC. ("Health Mart") is a Delaware corporation with its principal place of business in California. Health Mart operates as a subsidiary of McKesson Corporation. During all relevant times, Health Mart has sold and continues to sell prescription opioids in and around Idaho and in the communities adjacent to the Reservation. Health Mart is a franchising and marketing arm that has relationships with 4,700 retail pharmacies nationally, including in Idaho. Health Mart is authorized to conduct business in Idaho.

61. Collectively Defendants CVS, Walgreens, Walmart, Rite Aid, and Health Mart are referred to as "National Retail Pharmacies." AmerisourceBergen, Cardinal,

McKesson and the National Retail Pharmacies are collectively referred to as the "Distributor Defendants."[6]

62. Defendants include the above-referenced entities as well as their predecessors, successors, affiliates, subsidiaries, partnerships and divisions to the extent that they are engaged in the manufacture, promotion, distribution sale and/or dispensing or opioids.

III. JURISDICTION AND VENUE

63. Plaintiff brings this civil action in MDL No. 2804, entitled *In Re: National Prescription Opiate Litigation*. Plaintiff is filing this Complaint directly into the Northern District of Ohio as permitted by Paragraph 6(a) of this Court's Case Management Order No. 1, dated 04/11/2018.

64. This Court has subject-matter jurisdiction under 28 U.S.C. § 1331 because this action presents a federal question. This Court has supplemental jurisdiction over the state-law causes of action under 28 U.S.C. § 1367 because the state-law claims are part of the same case or controversy.

65. The District of Idaho has personal jurisdiction over all Defendants because all Defendants have substantial contacts and business relationships with the State of Idaho, including consenting to be sued in Idaho by registering an agent for service of process and/or obtaining a distributor license and have purposefully availed themselves of business opportunities within the State of Idaho, including by marketing, distributing, or selling prescription opioids within the State of Idaho and on and around the Reservation.

[6] Together, AmerisourceBergen, Cardinal, McKesson, Purdue, Actavis, Cephalon, Endo, and Mallinckrodt, are also sometimes referred to as "RICO Supply Chain Defendants."

66. The District of Idaho also has personal jurisdiction over all of the defendants under 18 U.S.C. § 1965(b). This Court may exercise nationwide jurisdiction over the named Defendants where the "ends of justice" require national service and Plaintiff demonstrates national contacts. Here, the interests of justice require that Plaintiff be allowed to bring all members of the nationwide RICO enterprise before the court in a single trial. *See Iron Workers Local Union No. 17 Insurance Fund v. Philip Morris Inc.*, 23 F. Supp. 2d 796 (1998).

67. Venue is proper in the District of Idaho under 28 U.S.C. § 1391(b) and 18 U.S.C. § 1965 because a substantial part of the events or omissions giving rise to this action occurred in this judicial district and because all Defendants are subject to this Court's exercise of personal jurisdiction. Plaintiff states that but for the Order permitting direct filing into the Northern District of Ohio pursuant to Case Management Order No. 1, dated April 11, 2018, Plaintiff would have filed in the United States District Court, District of Idaho.

IV. ADDITIONAL FACTUAL ALLEGATIONS

A. Overview of the Opioid Epidemic

68. The term "opioid" includes all drugs derived from the opium poppy. The United States Food and Drug Administration describes opioids as follows: "Prescription opioids are powerful pain-reducing medications that include prescription oxycodone, hydrocodone, and morphine, among others, and have both benefits as well as potentially serious risks. These medications can help manage pain when prescribed for the right

condition and when used properly. But when misused or abused, they can cause serious harm, including addiction, overdose, and death."[7]

69. Prescription opioids with the highest potential for addiction are listed under Schedule II of the Controlled Substances Act. This includes non-synthetic opium derivatives (such as codeine and morphine, also known generally as "opiates"), partially synthetic derivatives (such as hydrocodone and oxycodone), and fully synthetic derivatives (such as fentanyl and methadone).

70. Historically, opioids were considered too addictive and debilitating for the treatment of chronic pain, like back pain, migraines, and arthritis. According to Dr. Caleb Alexander, director of Johns Hopkins University's Center for Drug Safety and Effectiveness, "[opioids] have very, very high inherent risks . . . and there's no such thing as a fully safe opioid."[8]

71. Opioids also tend to induce tolerance, whereby a person who uses opioids repeatedly over time no longer responds to the drug as strongly as before, thus requiring a higher dose to achieve the same effect. This tolerance contributes to the high risk of overdose during a relapse.

72. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled

[7] *See* U.S. FDA, Opioid Medications, available at https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm337066.htm (last accessed December 19, 2017).

[8] Matthew Perrone et al., *Drugmakers push profitable, but unproven, opioid solution*, Center for Public Integrity, available at https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution (last accessed December 20, 2017).

with evidence of greater pain complaints as patients developed tolerance to opioids over time, and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

73. To take advantage of the much larger and more lucrative market for chronic pain patients, the Defendants had to change this.[9]

74. As described herein, Defendants engaged in conduct that directly caused doctors to unwittingly prescribe skyrocketing amounts of opioids. Defendants also intentionally neglected their obligations to prevent diversion of the highly addictive substance.

75. As a result of Defendants' wrongful conduct, the number of prescriptions for opioids increased sharply, reaching nearly 250,000,000 prescriptions in 2013, almost enough for every person in the United States to have a bottle of pills. This represents an increase of 300% since 1999. In 2015, Idaho providers wrote 76.4 opioid prescriptions per 100 persons.[10]

76. Many Americans, including Idahoans and members of the Tribe, are now addicted to prescription opioids. In 2016, drug overdoses killed over 60,000 people in the United States, an increase of more than 22 percent over the previous year. The New York Times reported in September 2017 that the opioid epidemic is now killing babies and toddlers because ubiquitous, deadly opioids are "everywhere" and are mistaken as

[9] *See* Harriet Ryan et al., '*You want a description of hell?' OxyContin's 12-hour problem*, L.A. Times (May 5, 2016), available at http://www.latimes.com/projects/oxycontin-part1/ (last accessed December 20, 2017).

[10] *See* Idaho Opioid Summary, available at https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/idaho-opioid-summary (last accessed January 25, 2019).

candy.[11] The opioid epidemic has been declared a public health emergency by the President of the United States.

77. The wave of addiction was created by the increase in opioid prescriptions. One in 4 Americans receiving long-term opioid therapy struggles with opioid addiction. Nearly 2 million Americans have a prescription opioid use disorder.

78. According to the NIH's National Institute on Drug Abuse, approximately 21 to 29 percent of patients prescribed opioids for chronic pain misuse them. Between 8 and 10 percent develop an opioid use disorder. Four to 6 percent of people who misuse prescription opioids transition to heroin abuse, and about 80 percent of people who use heroin first misused prescription opioids.

79. Deaths from prescription opioids have quadrupled in the past 20 years. In 2016, there were 119 opioid-related overdose deaths in Idaho – a rate of 7.4 deaths per 100,000 persons.[12]

80. Treatment admissions for abuse of opioids and emergency room visits for non-medical opioid use have also dramatically increased.

81. The increases in opioid deaths and treatments are directly tied to the prescribing practices created by Defendants. According to the CDC,[13] opioid deaths and treatment admissions are tied to opioid sales:

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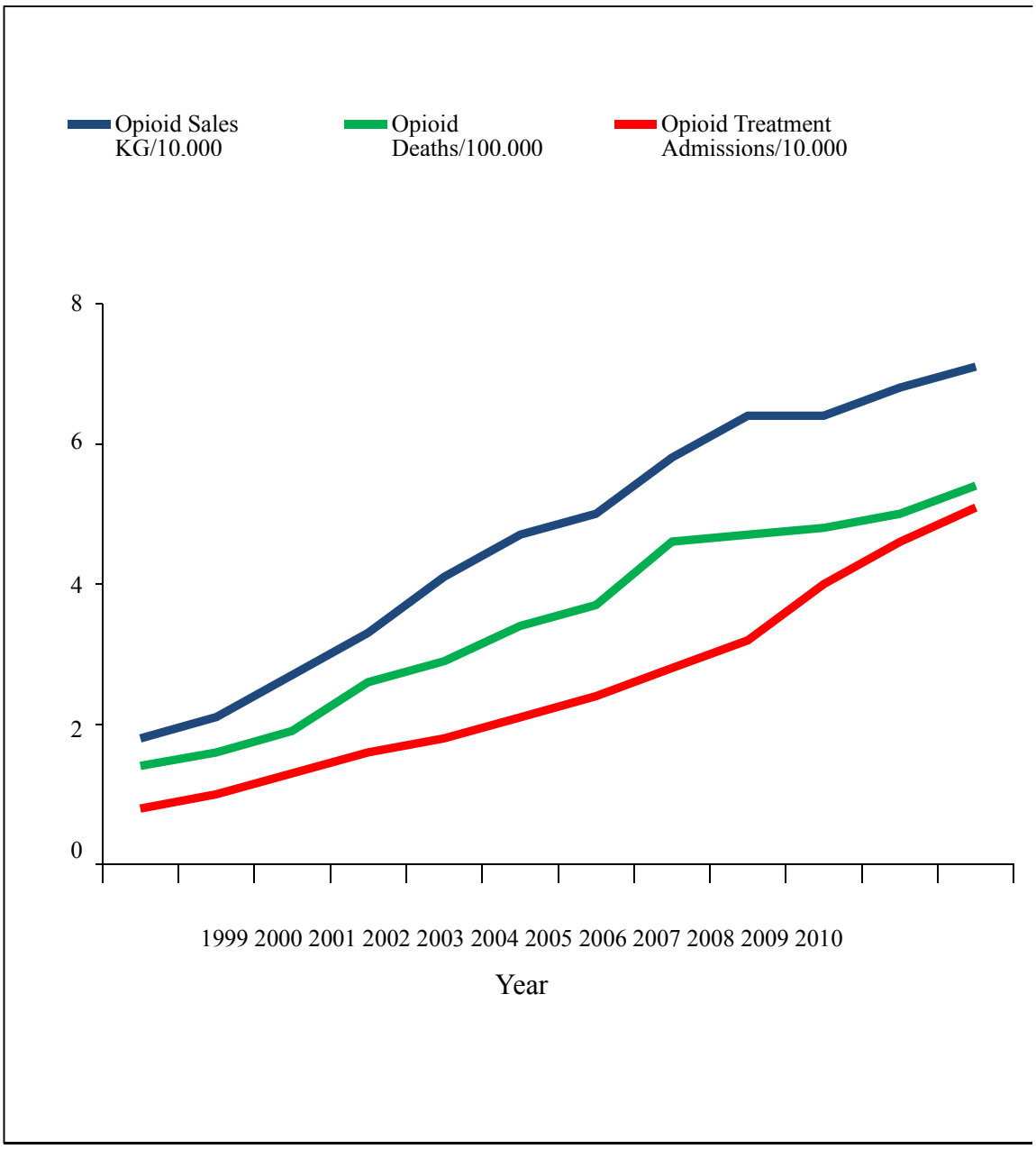
[11] Julie Turkewitz, *"The Pills are Everywhere:" How the Opioid Crisis Claims Its Youngest Victims*, N.Y. Times (Sept. 20, 2017), available at https://www.nytimes.com/2017/09/20/us/opioid-deaths-children.html (last accessed January 4, 2018).

[12] *See* IdahoOpioid Summary, available at https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/idaho-opioid-summary (last accessed January 25, 2019)

[13] U.S. Dep't of Health & Human Servs., *Addressing Prescription Drug Abuse in the United States*, available at https://www.cdc.gov/drugoverdose/pdf/hhs_prescription_drug_abuse_report_09.2013.pdf (last accessed December 29, 2017).



82. People who are addicted to prescription opioid painkillers are forty times more likely to be addicted to heroin. Heroin is pharmacologically similar to prescription opioids. Available data indicates that the nonmedical use of prescription opioids is a strong risk factor for heroin use. According to the CDC, heroin drug overdose deaths have more than tripled in the past four years. In Idaho, since 2014, heroin overdose deaths have

increased from 11 to 25 deaths – more than doubling – and from 2012 to 2016 deaths attributed to synthetic opioids (mainly fentanyl) increased similarly from 11 to 20 deaths.[14]

83. Heroin is pharmacologically similar to prescription opioids. Available data indicates that the nonmedical use of prescription opioids is a strong risk factor for heroin use. According to the CDC, heroin drug overdose deaths have more than tripled in the past four years. In Idaho, since 2014, heroin overdose deaths have increased from 11 to 25 deaths – more than doubling – and from 2012 to 2016 deaths attributed to synthetic opioids (mainly fentanyl) increased similarly from 11 to 20 deaths.[15]

84. Prescription opioid abuse "is a serious national crisis that affects public health as well as social and economic welfare." The economic burden of prescription opioid misuse alone is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice expenditures.[16]

85. Prescription opioid abuse disproportionately impacts American Indian communities, including the Tribe. The CDC reported in 2012 that 1 in 10 American Indians/Native Americans (over the age of 12) used prescription pain medicine for nonprescription purposes, compared with 1 in 20 whites and 1 in 30 African-Americans.[17]

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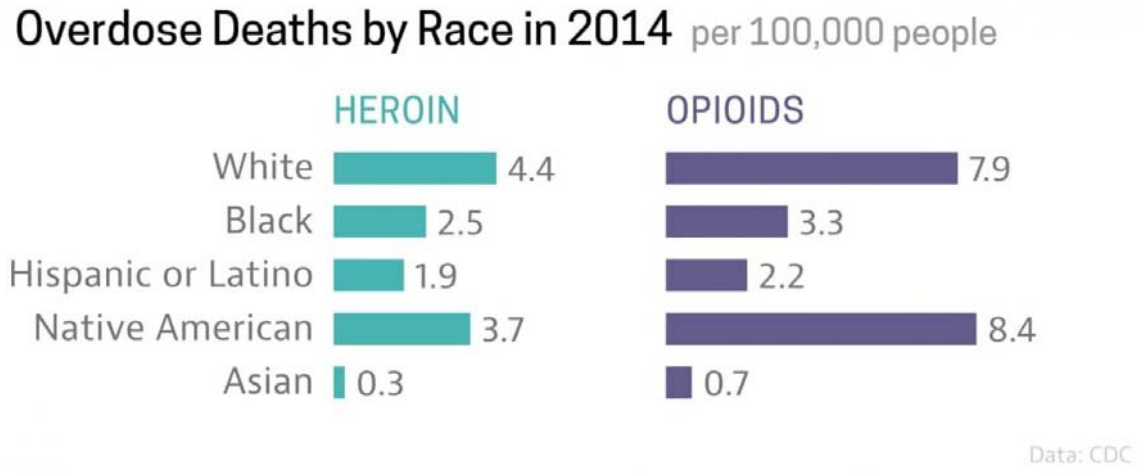
[14] *See* Idaho Opioid Summary, available at https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/idaho-opioid-summary (last visited January 25, 2019.

[15] *See* Idaho Opioid Summary, available at https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/idaho-opioid-summary (last visited January 25, 2019.

[16] Opioid Crisis, NIH, National Institute on Drug Abuse, available at https://www.drugabuse.gov/drugs-abuse/opioids/opioid-crisis (last accessed December 19, 2017).

[17] US Medicine (2012). IHS Grapples with Pervasive Prescription Opioid Misuse in Tribal Areas. Addiction, available at http://www.usmedicine.com/clinical-topics/addiction/ihs-grapples-with-pervasive-prescription-opioid-misuse-in-tribal-areas/ (last accessed December 19, 2017).

86. Drug overdose deaths among all Americans increased more than 200 percent between 1999 and 2015. In that same time, the death rate rose by more than 500 percent among Native Americans and native Alaskans:[18]

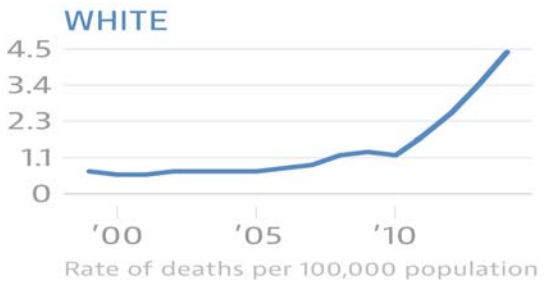


87. The death rate for heroin overdoses among Native Americans has also skyrocketed, rising by 236 percent from 2010 to 2014:[19]

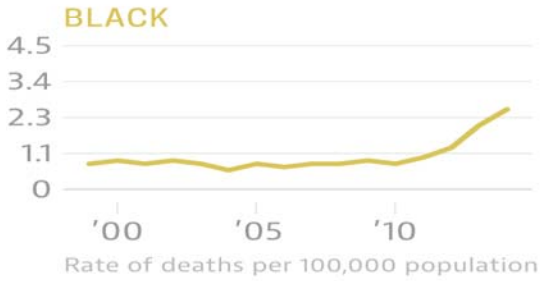
[18] Eugene Scott, *Native Americans, among the most harmed by the opioid epidemic, are often left out of the conversation*, Washington Post (Oct. 30, 2017), available at https://www.washingtonpost.com/news/the-fix/wp/2017/10/30/native-americans-among-the-most-harmed-by-the-opioid-epidemic-are-often-left-out-of-conversation/?utm_term=.3151c8bc8ecc (last accessed December 29, 2017).

[19] Dan Nolan and Chris Amico, *How Bad is the Opioid Epidemic?*, PBS.org (Feb. 23, 2016), available at https://www.pbs.org/wgbh/frontline/article/how-bad-is-the-opioid-epidemic/ (last accessed December 29, 2017).

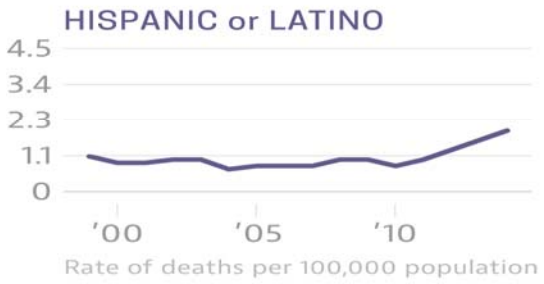
Rate of Deaths from Heroin Overdoses, by Race



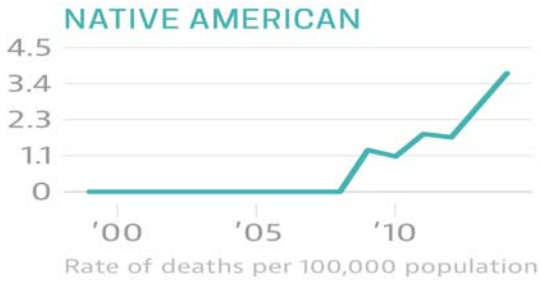
267%
increase from 2010–2014



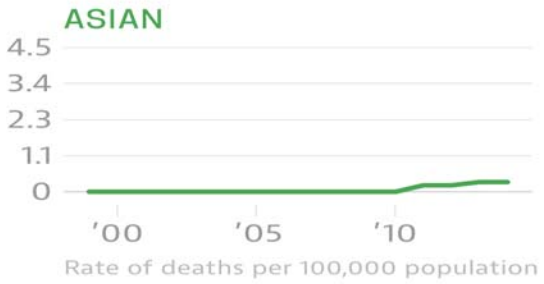
213%
increase from 2010–2014



137%
increase from 2010–2014



236%
increase from 2010–2014



Figures are too small to reliably calculate percentage increase.

Source: Centers for Disease Control

88. Idahoans, particularly those who reside in the parts of the state near the Tribe's community, have very limited access to opioid treatment programs.

B. The Manufacturer Defendants Spread False or Misleading Information About the Safety of Opioids

89. Each Manufacturer Defendant developed a well-funded marketing scheme based on deception to persuade doctors and patients that opioids can and should be used for treatment of chronic pain, resulting in opioid treatment for a far larger group of patients who are much more likely to become addicted. In connection with this scheme, each Manufacturer Defendant spent, and continued to spend, millions of dollars on promotional activities and materials that falsely denied or minimized the risks of opioids while overstating the benefit of using them for chronic pain.

90. The Manufacturer Defendants employed the same marketing plans and strategies and deployed the same messages in and around the state, including in Plaintiff's community, as they did nationwide. Across the pharmaceutical industry, corporate headquarters fund and oversee "core message" development on a national basis. This comprehensive approach ensures that the Manufacturer Defendants' messages are accurately and consistently delivered across marketing channels – including detailing visits, speaker events, and advertising – and in each sales territory. The Manufacturer Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

91. The deceptive marketing schemes included, among others, (a) false or misleading direct, branded advertisements; (b) false or misleading direct-to-physician marketing, also known as "detailing;" (c) false or misleading materials, speaker programs, webinars, and brochures; and (d) false or misleading unbranded advertisements

or statements by purportedly neutral third parties that were really designed and distributed by the Manufacturer Defendants. In addition to using third parties to disguise the source of their misinformation campaign, the Manufacturer Defendants also retained the services of certain physicians, known as "key opinion leaders" or "KOLs" to convince both doctors and patients that opioids were safe for the treatment of chronic pain.

92. The Manufacturer Defendants have made false and misleading claims, contrary to the language on their drugs' labels regarding the risks of using their drugs that: (a) downplayed the serious risk of addiction; (b) created and promoted the concept of "pseudoaddiction" when signs of actual addiction began appearing and advocated that the signs of addiction should be treated with more opioids; (c) exaggerated the effectiveness of screening tools to prevent addiction; (d) claimed that opioid dependence and withdrawal are easily managed; (e) denied the risks of higher dosages; and (f) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction. The Manufacturer Defendants have also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no scientifically reliable evidence to support the Manufacturer Defendants' claims.

93. The Manufacturer Defendants have disseminated these common messages to reverse the popular and medical understanding of opioids and risks of opioid use. They disseminated these messages directly, through their sales representatives, in speaker groups led by physicians the Manufacturer Defendants recruited for their support of their marketing messages, through unbranded marketing and through industry-funded front groups. And even though the Manufacturer Defendants knew doctors, healthcare

professionals and the medical community did not have a medical understanding of opioids and risks of opioid abuse, they did not disseminate messages consistent with their product labels that were designed and intended to instruct doctors on the proper use of their opioid products and underscore the abuse and addiction risks associated with those products in order that they would change their prescribing habits so their products would be safely used.

94. These statements were not only unsupported by or contrary to the scientific evidence, they were also contrary to pronouncements by and guidance from the FDA and CDC based on that same evidence.

95. The Manufacturer Defendants began their marketing schemes decades ago and continue them today.

96. As discussed herein, the 2016 CDC Guideline makes it patently clear that their schemes were and continue to be deceptive.

97. On information and belief, as a part of their deceptive marketing scheme, the Manufacturer Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the U.S., including in Idaho.

98. For example, on information and belief, the Manufacturer Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be schooled in treating pain and the risks and benefits of opioids and therefore more likely to accept the Manufacturer Defendants' misrepresentations.

99. On information and belief, the Manufacturer Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain.

100. The Manufacturer Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observed that existing evidence showed that elderly patients taking opioids suffer from elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse drug effects and interactions. The Guideline therefore concluded that there are special risks of long-term opioid use for elderly patients and recommended that doctors use "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients. The same is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for posttraumatic stress disorder, which interact dangerously with opioids.

101. To increase the impact of their deceptive marketing schemes, on information and belief the Manufacturer Defendants coordinated and created unified marketing plans to ensure that the Manufacturer Defendants' messages were consistent and effective across all their marketing efforts.

102. Defendants' efforts have been wildly successful. Opioids are now the most prescribed class of drugs. Opioid sales in the United States have exceeded $8 billion in revenue annually since 2009.[20] In an open letter to the nation's physicians in August 2016, the then-U.S. Surgeon General expressly connected this "urgent health crisis" to

[20] *See* Katherine Eban, *Oxycontin: Purdue Pharma's Painful Medicine*, Fortune, (Nov. 9, 2011); David Crow, *Drugmakers Hooked on 10bn Opioid Habit*, Fin. Times (August 10, 2016).

heavy marketing of opioids to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."[21]

103. The Manufacturer Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

1. The Manufacturer Defendants Engaged in False and Misleading Direct Marketing of Opioids

104. The Manufacturer Defendants' direct marketing of opioids generally proceeded on two tracks: advertising campaigns and direct-to-physician marketing.

105. First, each Manufacturer Defendant conducted and continues to conduct advertising campaigns touting the purported benefits of its branded drugs. For example, upon information and belief, the Manufacturer Defendants spent more than $14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001.

106. A number of the Manufacturer Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example:

a. Endo, on information and belief, has distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker and chef, misleadingly implying that the drug would provide long-term pain-relief and functional improvement.

b. On information and belief, Purdue also ran a series of ads, called "Pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively.

[21] Murthy, supra note 3.

107. Although Endo and Purdue agreed in late 2015 and 2016 to halt these misleading representations in New York, they continued to disseminate them elsewhere.

108. The direct advertising disseminated by the Manufacturer Defendants did not disclose studies that were not favorable to their products, nor did they disclose that they did not have clinical evidence to support many of their claims.

2. The Manufacturer Defendants Used Detailing and Speaker Programs to Spread False and Misleading Information About Opioids

109. Second, each Manufacturer Defendant promoted the use of opioids for chronic pain through "detailers" – sophisticated and specially trained sales representatives who visited individual doctors and medical staff in their offices – and small group speaker programs.

110. The Manufacturer Defendants invested heavily in promoting the use of opioids for chronic pain through detailers and small group speaker programs.

111. The Manufacturer Defendants devoted massive resources to direct sales contacts with doctors. Upon information and belief, the Manufacturer Defendants spent in excess of $168 million in 2014 alone on detailing branded opioids to doctors, more than twice what they spent on detailing in 2000.

112. On information and belief, these detailers have spread and continue to spread misinformation regarding the risks and benefits of opioids to hundreds of thousands of doctors, including doctors in Idaho. For example, on information and belief, the Manufacturer Defendants' detailers, over the past two years, continue to falsely and misleadingly:

a. Describe the risk of addiction as low or fail to disclose the risk of addiction;

b. Describe their opioid products as "steady state" – falsely implying that these products are less likely to produce the high and lows that fuel addiction – or as less likely to be abused or result in addiction;

c. Tout the effectiveness of screening or monitoring patients as a strategy for managing opioid abuse and addiction;

d. State that there is no maximum dose and that doctors can safely increase doses without disclosing the significant risks to patients at higher doses;

e. Discuss "pseudoaddiction";

f. State that patients would not experience withdrawal if they stopped using their opioid products;

g. State that their opioid products are effective for chronic pain without disclosing the lack of evidence for the effectiveness of long-term opioid use; and

h. State that abuse-deterrent formulations are tamper- or crush-resistant and harder to abuse or misuse.

113. Because these detailers must adhere to scripts and talking points drafted by the Manufacturer Defendants, it can be reasonably inferred that most, if not all, of the Manufacturer Defendants' detailers made and continue to make these misrepresentations to the thousands of doctors they have visited and continue to visit. The Manufacturer Defendants have not corrected this misinformation.

114. The Manufacturer Defendants' detailing to doctors was highly effective in the national proliferation of prescription opioids. On information and belief, the Manufacturer Defendants used sophisticated data mining and intelligence to track and understand the rates of initial prescribing and renewal by individual doctors, allowing specific and individual targeting, customizing, and monitoring of their marketing.

115. The Manufacturer Defendants also identified doctors to serve, for payment and other remuneration, on their speakers' bureaus and to attend programs with speakers

and meals paid for by the Manufacturer Defendants. These speakers gave the false impression that they were providing unbiased and medically accurate presentations when they were, in fact, presenting a script prepared by the Manufacturer Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct the Manufacturer Defendants' prior misrepresentations about the risks and benefits of opioids.

116. Each Manufacturer Defendant devoted and continues to devote massive resources to direct sales contacts with doctors.

117. Marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. On information and belief, frequent prescribers are generally more likely to have received a detailing visit, and in some instances, infrequent prescribers of opioids received a detailing visit from a Manufacturer Defendant's detailer and then prescribed only that Manufacturer Defendant's opioid products.

118. The FDA has cited at least one Manufacturer Defendant for deceptive promotions by its detailers and direct-to-physician marketing. In 2010, the FDA notified Actavis that certain brochures distributed by Actavis were "false or misleading because they omit and minimize the serious risks associated with the drug, broaden and fail to present the limitations to the approved indication of the drug, and present unsubstantiated superiority and effectiveness claims." The FDA also found that "[t]hese violations are a concern from a public health perspective because they suggest that the product is safer and more effective than has been demonstrated."[22]

[22] Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Commc'ns, U.S. Food & Drug Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf (last accessed December 29, 2017).

3. The Manufacturer Defendants Deceptively Marketed Opioids through Unbranded Advertising Disseminated by Seemingly Independent Third Parties Which Was Really Created by the Manufacturer Defendants

119. The Manufacturer Defendants also deceptively marketed opioids through unbranded advertising – i.e., advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, the Manufacturer Defendants coordinated and controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain.

120. The extent of the financial ties between the opioid industry and third-party advocacy groups is stunning. A recent report released by the United States Senate Homeland Security and Governmental Affairs Committee reveals nearly $9 million in payments from companies including Purdue and Janssen to 14 outside groups between 2012 and 2017.[23] According to the report, "[t]he fact that . . . manufacturers provided millions of dollars to the groups described below suggests, at the very least, a direct link between corporate donations and the advancement of opioids-friendly messaging." The report concluded that "many of the groups described in this report may have played a significant role in creating the necessary conditions for the U.S. opioids epidemic."

121. The Manufacturer Defendants marketed opioids through third-party, unbranded advertising to avoid regulatory scrutiny because such advertising is not

[23] *See* Scott Neuman & Alison Kodjak, *Drugmakers Spend Millions Promoting Opioids To Patient Groups, Senate Report Says*, NPR.org (Feb. 13, 2018), available at https://www.npr.org/sections/thetwo-way/2018/02/13/585290752/drugmakers-spent-millions-promoting-opioids-to-patient-groups-senate-report-says (last accessed February 23, 2018).

submitted to and typically is not reviewed by the FDA. The Manufacturer Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like tobacco companies, the Manufacturer Defendants used third parties that they funded, directed, and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long-term opioid use for chronic pain.

122. The Manufacturer Defendants' deceptive unbranded marketing often contradicted what they said in their branded materials reviewed by the FDA.

123. The Manufacturer Defendants also spoke through a small circle of doctors—KOLs—who, upon information and belief, were selected, funded, and elevated by the Manufacturer Defendants because their public positions supported the use of opioids to treat chronic pain.

124. Pro-opioid doctors are one of the most important avenues that the Manufacturer Defendants use to spread their false and misleading statements about the risks and benefits of long-term opioid use. The Manufacturer Defendants know that doctors rely heavily and more uncritically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy.

125. For example, the New York Attorney General ("NY AG") found in its settlement with Purdue that through March 2015, the Purdue website *In the Face of Pain* failed to disclose that doctors who provided testimonials on the site were paid by Purdue,[24] and concluded that Purdue's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.

[24] *See* New York State Office of the Attorney General, *A.G. Schneiderman Announces Settlement with Purdue Pharma That Ensures Responsible and Transparent Marketing Of*

126. Pro-opioid KOLs have admitted to making false claims about the effectiveness of opioids. Dr. Russell Portenoy received research support, consulting fees, and other compensation from Cephalon, Endo, Janssen, and Purdue, among others. Dr. Portenoy admitted that he "gave innumerable lectures . . . about addictions that weren't true." His lectures falsely claimed that fewer than 1 percent of patients would become addicted to opioids. Dr. Portenoy admitted that the primary goal was to "destigmatize" opioids, and he conceded that "[d]ata about the effectiveness of opioids does not exist." According to Dr. Portenoy, "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did." Dr. Portenoy admitted that "[i]t was clearly the wrong thing to do."[25]

127. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations, such as his claim that "the likelihood that the treatment of pain using an opioid drug which is prescribed by a doctor will lead to addiction is extremely low." He appeared on Good Morning America in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely-watched program, broadcast across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very

Prescription Opioid Drugs By The Manufacturer (August 20, 2015), available at https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-purdue-pharma-ensures-responsible-and-transparent (last accessed December 20, 2017).

[25] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J. (Dec. 17, 2012), available at https://www.wsj.com/articles/SB10001424127887324478304578173342657044604 (last accessed December 20, 2017).

major psychiatric disorder, most doctors can feel very assured that the person is not going to become addicted."[26]

128. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr. Webster was President of the American Academy of Pain Medicine ("AAPM") in 2013. He is a Senior Editor of Pain Medicine, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo and Purdue. At the same time, Dr. Webster was receiving significant funding from the Manufacturer Defendants (including nearly $2 million from Cephalon).

129. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, a five-question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and, for this reason, references to screening appear in various industry supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Endo, Janssen and Purdue. Unaware of the flawed science and industry bias underlying this tool, certain states and public entities have incorporated the Opioid Risk Tool into their own guidelines, indicating, also, their reliance on the Manufacturer Defendants and those under their influence and control.

[26] Good Morning America (ABC television broadcast Aug. 30, 2010).

130. In 2011, Dr. Webster presented via webinar a program sponsored by Purdue entitled "Managing Patient's Opioid Use: Balancing the Need and the Risk." Dr. Webster recommended the use of risk screening tools, urine testing and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach doctors in the Tribe's community and doctors treating members of the Tribe's community.[27]

131. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain. In Dr. Webster's description, the only way to differentiate the two was to increase a patient' dose of opioids. As he and co-author Beth Dove wrote in their 2007 book *Avoiding Opioid Abuse While Managing Pain*—a book that is still available online—when faced with signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response."[28] Upon information and belief, Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."[29]

132. The Manufacturer Defendants cited and promoted favorable studies or articles by their KOLs. By contrast, Manufacturer Defendants did not support,

[27] *See* Emerging Solutions in Pain, *Managing Patient's Opioid Use: Balancing the Need and the Risk*, available at http://www.emergingsolutionsinpain.com/ce-education/opioid management?option=com_continued&view=frontmatter&Itemid=303&course=209 (last visited Aug. 22, 2017).

[28] Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain* (2007).

[29] John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J. Sentinel, (Feb. 18, 2012).

acknowledge, or disseminate publications of doctors unsupportive or critical of chronic opioid therapy.

133. On information and belief, the Manufacturer Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of the Manufacturer Defendants, these "Front Groups" – which include, but are not limited to, the American Pain Foundation ("APF")[30] and the American Academy of Pain Medicine – generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. The evidence did not support these guidelines, materials, and programs at the time they were created, and the scientific evidence does not support them today. Indeed, they stand in marked contrast to the 2016 CDC Guideline.

134. The Manufacturer Defendants worked together, through Front Groups, to spread their deceptive messages about the risks and benefits of long-term opioid therapy.

135. Indeed, the Manufacturer Defendants spent millions on the Front Groups to generate false opioid-friendly messaging.[31] The amount of industry funding, and its sources, is obscured by a lack of transparency on behalf of both the opioid industry and the Front Groups.

136. On information and belief, these Front Groups also assisted the Manufacturer Defendants by responding to negative articles, by advocating against regulatory or legislative changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by the Manufacturer Defendants.

[30] Dr. Portenoy was a member of the board of the APF.
[31] *See* Neuman & Kodjack, *supra* note 23.

137. These Front Groups depended on the Manufacturer Defendants for funding and, in some cases, for survival. On information and belief, the Manufacturer Defendants exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. In doing so, the Manufacturer Defendants made sure that the Front Groups would generate only the messages the Manufacturer Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent and serving the needs of their members – whether patients suffering from pain or doctors treating those patients.

138. Defendants Teva, Endo, Janssen and Purdue, in particular, utilized multiple Front Groups, including many of the same ones. Several of the most prominent are described below, but there are many others, including the American Pain Society ("APS"), American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), the Center for Practical Bioethics ("CPB"), the U.S. Pain Foundation ("USPF") and the Pain & Policy Studies Group ("PPSG").[32]

139. Organizations, including the U.S. Senate Finance Committee, began to investigate the American Pain Foundation ("APF") in 2012 to determine the links, financial and otherwise, between the organization and the opioid industry.[33] The investigation revealed that APF received 90 percent of its funding from the drug and

[32] *See generally, e.g.*, Letter from Sen. Ron Wyden, U.S. Senate Comm. on Fin., to Sec. Thomas E. Price, U.S. Dep't of Health and Human Servs., (May 5, 2015).

[33] Charles Ornstein & Tracy Weber, *Senate Panel Investigates Drug Companies Ties to Pain Groups*, Wash. Post (May 8, 2012), available at https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-paid-groups/2012/05/08/gIQA2X4qBU_story.html (last accessed December 19, 2017).

medical-device industry, and "its guides for patients, journalists and policymakers had played down the risks associated with opioid painkillers while exaggerating the benefits from the drugs." Within days, APF dissolved "due to irreparable economic circumstances."

140. Another front group for the Manufacturer Defendants was the American Academy of Pain Medicine ("AAPM"). With the assistance, prompting, involvement, and funding of the Manufacturer Defendants, the AAPM issued purported treatment guidelines and sponsored and hosted medical education programs essential to the Manufacturer Defendants' deceptive marketing of chronic opioid therapy.

141. AAPM received substantial funding from opioid manufacturers. For example, AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allowed drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event.

142. Upon information and belief, AAPM is viewed internally by Endo as "industry friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The

conferences sponsored by AAPM heavily emphasized sessions on opioids – 37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs Perry Fine and Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation.

143. The Manufacturer Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

144. In 1996, AAPM and APS jointly issued a consensus statement, "The Use of Opioids for the Treatment of Chronic Pain," which endorsed opioids to treat chronic pain and claimed that the risk of a patients' addiction to opioids was low. Dr. Haddox, who co-authored the AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011, and, upon information and belief, was taken down from AAPM's website only after a doctor complained.[34]

145. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain.[35] Treatment guidelines have been relied upon by doctors, especially the general practitioners and family doctors targeted by the Manufacturer Defendants. Treatment guidelines not only directly inform doctors' prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in determining

[34] *The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement From the American Academy of Pain Medicine and the American Pain Society*, 13 Clinical J. Pain 6 (1997).

[35] Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain*, 10 J. Pain 113 (2009).

whether they should cover treatments for specific indications. Pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment guidelines with doctors during individual sales visits.

146. At least 14 of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Cephalon, Endo, and Purdue. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories.[36] One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Manufacturer Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited hundreds of times in academic literature, were disseminated in the Tribe's community during the relevant time period, are still available online, and were reprinted in the Journal of Pain. The Manufacturer Defendants widely referenced and promoted the 2009 Guidelines without disclosing the lack of evidence to support them or the Manufacturer Defendants financial support to members of the panel.

[36] *Id.*

147. On information and belief, the Manufacturer Defendants combined their efforts through the Pain Care Forum ("PCF"), which began in 2004 as an APF project. PCF is comprised of representatives from opioid manufacturers (including Endo, Janssen, and Purdue) and various Front Groups, almost all of which received substantial funding from the Manufacturer Defendants. Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids was not unacceptably negative and did not require mandatory participation by prescribers. PCF also worked to address a lack of coordination among its members and developed cohesive industry messaging.

148. On information and belief, through Front Groups and KOLs, the Manufacturer Defendants wrote or influenced prescribing guidelines that reflected the messaging the Manufacturer Defendants wanted to promote rather than scientific evidence.

149. Through these means, and likely others still concealed, the Manufacturer Defendants collaborated to spread deceptive messages about the risks and benefits of long-term opioid use.

C. The Manufacturer Defendants' Statements about the Safety of Opioids Were Patently False

150. The Manufacturer Defendants' misrepresentations reinforced each other and created the dangerously misleading impressions that: (a) starting patients on opioids was low-risk because most patients would not become addicted, and because those who were at greatest risk of addiction could be readily identified and managed; (b) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (c) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks;

and (d) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive.

151. Some examples of these false claims include:

a. Actavis's predecessor caused a patient education brochure, Managing Chronic Back Pain, to be distributed beginning in 2003, which admitted that opioid addiction is possible, but falsely claimed that it is "less likely if you have never had an addiction problem." Based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, it appears that Actavis continued to use this brochure in 2009 and beyond.

b. Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which suggests that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative prescriptions, or theft. This publication is available today.[37]

c. Endo sponsored a website, "PainKnowledge," which, upon information and belief, claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Upon information and belief, another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them." Endo also distributed an "Informed Consent" document on PainAction.com, which misleadingly suggested that only people who "have problems with substance abuse and addiction" are likely to become addicted to opioid medications.

d. Upon information and belief, Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that "[m]ost health care providers who treat people with pain agree that most people do not develop an addiction problem."

e. Janssen reviewed and distributed a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."

[37] Available at https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf (last accessed December 19, 2017).

f. Janssen currently runs a website, *Prescriberesponsibly.com* (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated."[38]

g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* – which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "misconceptions about opioid addiction[]." This publication is still available online.[39]

h. Consistent with the Manufacture Defendants' published marketing materials, upon information and belief, detailers for the Manufacturer Defendants in Idaho have minimized or omitted and continue to minimize or omit any discussion with doctors or their medical staff in Idaho about the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

152. The Manufacturer Defendants engaged in this campaign of misinformation in an intentional effort to deceive doctors and patients and thereby increase the use of their opioid products.

153. The Manufacturer Defendants' misrepresentations have been conclusively debunked by the FDA and CDC, and are contrary to longstanding scientific evidence.

154. As noted in the 2016 CDC Guideline[40] endorsed by the FDA, there is "extensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction])." The Guideline points out that "[o]pioid pain medication use presents serious risks, including . . . opioid use disorder" and that

[38] Available at, http://www.prescriberesponsibly.com/articles/opioid-pain-management (last accessed December 19, 2017).

[39] Available at, http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf (last accessed December 20, 2017).

[40] Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, Morbidity & Mortality Wkly Rep. (Mar. 18, 2016) [hereinafter 2016 CDC Guideline], available at https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm (last accessed December 20, 2017).

"continuing opioid therapy for three (3) months substantially increases risk for opioid use disorder."

155. The FDA further exposed the falsity of Defendants' claims about the low risk of addiction when it announced changes to the labels for extended-release/long-acting opioids in 2013 and for immediate-release opioids in 2016. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." (emphasis added).[41] According to the FDA, because of the "known serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed. (emphasis added). The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction "can occur in patients appropriately prescribed [opioids]."

156. The Manufacturer Defendants have been, and are, aware that their misrepresentations about opioids are false.

[41] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food & Drug Admin., U.S. Dep't of Health and Human Servs., to Andrew Koldny, M.d., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), available at https://www.regulations/gov/contentStreamer?documentId=FDA-2012-P-0818-0793&attachmentNumber=1&contentType=pdf (last accessed December 19, 2017); Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food & Drug Admin., U.S. Dep't of Health and Human Servs., to Peter R. Mathers & Jennifer A. Davidson, Kleinfeld, Kaplan & Becker, LLP (Mar. 22, 2016), available at https://www.regulations.gov/contentStreamer?documentId=FDA-2014-P-0205-0006&attachmentNumber=1&contentType=pdf (last accessed December 19, 2017).

157. The NY AG, in a 2016 settlement agreement with Endo, found that opioid "use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder."[42] Endo had claimed on its www.opana.com website that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," but the NY AG found that Endo had no evidence for that statement. Consistent with this, Endo agreed not to "make statements that . . . opioids generally are non-addictive" or "that most patients who take opioids do not become addicted" in New York.

158. The Manufacturer Defendants falsely instructed doctors and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. The Manufacturer Defendants called this phenomenon "pseudoaddiction" – a term coined by Dr. David Haddox, who went to work for Purdue, and popularized by Dr. Portenoy – and falsely claimed that pseudoaddiction is substantiated by scientific evidence. Some illustrative examples of these deceptive claims are described below:

a. Cephalon and Purdue sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction. The 2012 edition of *Responsible Opioid Prescribing* remains for sale online.[43]

b. On information and belief, Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: "pseudoaddiction . . .

[42] Assurance of Discontinuance, *In re Endo Health Solutions Inc. and Endo Pharm. Inc.* (Assurance No. 15-228), at 13, available at https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf (last accessed December 19, 2017).

[43] *See* Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician's Guide* (2d ed. 2012).

refers to patient behaviors that may occur when pain *is under-treated* . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."

c. Endo sponsored a National Initiative on Pain Control ("NIPC") CME program in 2009 entitled "Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia," which, upon information and belief, promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo appears to have substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.

d. Purdue published a pamphlet in 2011 entitled Providing Relief, Preventing Abuse, which, upon information and belief, described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug- seeking behaviors] in patients who have pain that has not been effectively treated."

e. Upon information and belief, Purdue sponsored a CME program titled "Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse." In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long acting opioid.

159. Pseudoaddiction is fictional. The 2016 CDC Guideline rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid dosages be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use," and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."

160. In connection with its settlement with the NY AG, Endo was forced to admit that the concept of pseudoaddiction was a sham. In finding that "[t]he

pseudoaddiction concept has never been empirically validated and in fact has been abandoned by some of its proponents," the NY AG, in its 2016 settlement with Endo, reported that despite the fact that Endo trained its sales representative to use the concept of pseudoaddiction, "Endo's Vice President for Pharmacovigilance and Risk Management testified to [the NY AG] that he was not aware of any research validating the 'pseudoaddiction' concept" and acknowledged the difficulty in distinguishing "between addiction and 'pseudoaddiction.'"[44]

161. The Manufacturer Defendants falsely instructed doctors and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies would allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because the Manufacturer Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. The Manufacturer Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain. Some illustrative examples of these deceptive claims are described below:

a. On information and belief, Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo's speakers bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

b. On information and belief, Purdue sponsored a November 2011 webinar, *Managing Patient's Opioid Use: Balancing the Need and Risk*, which

[44] *See supra* note 42, at 7.

claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."

c. On information and belief, as recently as 2015, Purdue has represented in scientific conferences that "bad apple" patients – and not opioids – are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

d. On information and belief, detailers for the Manufacturer Defendants have touted and continue to tout to doctors in Idaho the reliability and effectiveness of screening or monitoring patients as a tool for managing opioid abuse and addiction.

162. Once again, the 2016 CDC Guideline confirms that these statements were false, misleading, and unsupported at the time they were made by the Manufacturer Defendants. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies – such as screening tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and deter abuse – "for improving outcomes related to overdose, addiction, abuse, or misuse." As a result, the Guideline recognizes that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy." (emphasis added).

163. To underplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, the Manufacturer Defendants falsely claimed that opioid dependence could easily be addressed by tapering and that opioid withdrawal was not a problem, and failed to disclose the increased difficulty of stopping opioids after long-term use.

164. For example, on information and belief, a 2011 non-credit educational program sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that

withdrawal symptoms could be avoided by tapering a patient's opioid dose by 10%-20% for 10 days.

165. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation" without mentioning any hardships that might occur.[45]

166. The Manufacturer Defendants deceptively minimized the significant symptoms of opioid withdrawal – which, as explained in the 2016 CDC Guideline, include drug craving, anxiety, insomnia, abdominal pain, vomiting, diarrhea, tremor, and tachycardia (rapid heartbeat) – and grossly understated the difficulty of tapering, particularly after long-term opioid use.

167. Contrary to the Manufacturer Defendants' representations, the 2016 CDC Guideline recognizes that the duration of opioid use and the dosage of opioids prescribed should be "limit[ed]" to "minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms," because "physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days." (emphasis added). The Guideline further states that "more than a few days of exposure to opioids significantly increases hazards" and "each day of unnecessary opioid use increases likelihood of physical dependence without adding benefit."

168. The Manufacturer Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to

[45] Available at, http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf (last accessed December 19, 2017).

the Manufacturer Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. Some illustrative examples of these deceptive claims are described below:

a. On information and belief, Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction."

b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claimed that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. This guide is still available online.[46]

c. Endo sponsored a website, "PainKnowledge," which, upon information and belief, claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain."

d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004 Endo Pharmaceuticals PM-0120). In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . .You won't 'run out' of pain relief."[47]

e. Janssen, on information and belief, sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages.

f. On information and belief, Purdue's *In the Face of Pain* website promoted the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.

g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes

[46] Available at, https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf (last accessed December 19, 2017).

[47] Margo McCaffery & Chris Pasero, Endo Pharm., *Understanding Your Pain: Taking Oral Opioid Analgesics* (Russell K Portenoy, M.D., ed., 2004).

necessary," even unlimited ones, but did not disclose the risks from high opioid dosages. This publication is still available online.[48]

h. In 2007, Purdue sponsored a CME entitled "Overview of Management Options," which was available for CME credit and available until at least 2012. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.

i. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Front Group APF and others argued to the United States Fourth Circuit Court of Appeals that "there is no 'ceiling dose'" for opioids.[49]

j. On information and belief, Purdue's detailers have told doctors in Idaho that they should increase the dose of OxyContin, rather than the frequency of use, to address early failure.

169. These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages." The CDC also states that there are "increased risks for opioid use disorder, respiratory depression, and death at higher dosages."

170. The Manufacturer Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can prevent and curb addiction and abuse.

171. These abuse deterrent formulations (AD opioids) purportedly are harder to crush, chew, or grind; they become gelatinous when combined with a liquid, making

[48] Available at, http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf (last accessed December 19, 2017).

[49] Brief of the APF et al. in support of Appellant, *United States v. Hurowitz*, No. 05-4474, at 9 (4th Cir. Sept. 8, 2005).

them harder to inject, or contain a counteragent such as naloxone that is activated if the tablets are tampered. Despite this, AD opioids can be defeated – often quickly and easily – by those determined to do so. The 2016 CDC Guideline state that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies—even when they work—do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes. Moreover, they do not reduce the rate of misuse and abuse by patients who become addicted after using opioids long-term as prescribed or who escalate their use by taking more pills or higher doses. Tom Frieden, the Director of the CDC, has further reported that his staff could not find "any evidence showing the updated opioids [ADFs] actually reduce rates of addiction, overdoses, or death."[50]

172. Despite this lack of evidence, the Manufacturer Defendants have made and continue to make misleading claims about the ability of their so-called abuse-deterrent opioid formulations to prevent or reduce abuse and addiction and the safety of these formulations.

173. For example, Endo has marketed Opana ER[51] as tamper- or crush-resistant and less prone to misuse and abuse since even though: (a) on information and belief, the

[50] Matthew Perrone et al., *Drugmakers push profitable, but unproven, opioid solution*, Center for Public Integrity (Dec. 15, 2016), available at https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution (last accessed December 20, 2017).

[51] Because Opana ER could be "readily prepared for injection" and was linked to outbreaks of HIV and a serious blood disease, in May 2017, an FDA advisory committee recommended that Opana ER be withdrawn from the market. The FDA adopted this recommendation on June 8, 2017 and requested that Endo withdraw Opana ER from the market. Press Release, "FDA requests removal of Opana ER for risks related to abuse," June 8, 2017, available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm (last accessed December 20, 2017).

FDA warned in a 2013 letter that there was no evidence that Opana ER would provide a reduction in oral, intranasal or intravenous abuse; and (b) Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground up and chewed. Nonetheless, Endo's advertisements for Opana ER falsely claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. And on information and belief, detailers for Endo have informed doctors that Opana ER is harder to abuse.

174. In its 2016 settlement with the NY AG, Endo agreed not to make statements in New York that Opana ER was "designed to be, or is crush resistant." The NY AG found those statements false and misleading because there was no difference in the ability to extract the narcotic from Opana ER. The NY AG also found that Endo failed to disclose its own knowledge of the crushability of redesigned Opana ER in its marketing to formulary committees and pharmacy benefit managers.

175. Likewise, Purdue has engaged and continues to engage in deceptive marketing of its AD opioids – i.e., reformulated Oxycontin and Hysingla. Before April 2013, Purdue did not market its opioids based on their abuse deterrent properties. However, beginning in 2013 and continuing today, detailers from Purdue regularly use the so-called abuse deterrent properties of Purdue's opioid products as a primary selling point to differentiate those products from their competitors. Specifically, on information and belief, these detailers: (a) falsely claim that Purdue's AD opioids prevent tampering and cannot be crushed or snorted; (b) falsely claim that Purdue's AD opioids prevent or reduce opioid misuse, abuse, and diversion, are less likely to yield a euphoric high, and are disfavored by opioid abusers; (c) falsely claim Purdue's AD opioids are "safer" than

other opioids; and (d) fail to disclose that Purdue's AD opioids do not impact oral abuse or misuse and that its abuse deterrent properties can be defeated.

176. These statements and omissions by Purdue are false and misleading. Purdue knew and should have known that reformulated OxyContin is not better at tamper resistance than the original OxyContin and is still regularly tampered with and abused. A 2015 study also shows that many opioid addicts are abusing Purdue's AD opioids through oral intake or by defeating the abuse deterrent mechanism. Indeed, *one-third* of the patients in the study defeated the abuse deterrent mechanism and were able to continue inhaling or injecting the drug. And to the extent that the abuse of Purdue's AD opioids was reduced, those addicts simply shifted to other drugs such as heroin.[52] Despite this, J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's AD opioids are being abused in large numbers.[53]

177. The development, marketing, and sale of AD opioids is a continuation of the Manufacturer Defendants' strategy to use misinformation to drive profit. The Manufacturer Defendants' claims that AD opioids are safe falsely assuage doctors' concerns about the toll caused by the explosion in opioid abuse, causing doctors to prescribe more AD opioids, which are far more expensive than other opioid products even though they provide little or no additional benefit.

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[52] Cicero, Theodore J., and Matthew S. Ellis, "Abuse-deterrent formulations and the prescription opioid abuse epidemic in the United States: lessons learned from Oxycontin" (2015) 72.5 *JAMA Psychiatry* 424-430.

[53] *See* Harrison Jacobs, *There is a big problem with the government's plan to stop the drug-overdose epidemic*, Business Insider (Mar. 14, 2016), available at http://www.businessinsider.com/robert-califf-abuse-deterrent-drugs-have-a-big-flaw-2016-3 (last accessed December 20, 2017).

D. The Manufacturer Defendants Misrepresented the Benefits of Chronic Opioid Therapy

178. To convince doctors and patients that opioids should be used to treat chronic pain, the Manufacturer Defendants also had to persuade them that there was a significant upside to long-term opioid use.

179. The 2016 CDC Guideline makes clear, there is "insufficient evidence to determine long-term benefits of opioid therapy for chronic pain." In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use.

180. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks."

181. Despite this, the Manufacturer Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence. Not only have the Manufacturer Defendants failed to correct these false and misleading claims, they continue to make them today.

182. For example, the Manufacturer Defendants falsely claimed that long-term opioid use improved patients' function and quality of life. Some illustrative examples of these deceptive claims are described below:

a. On information and belief, Actavis distributed an advertisement that claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.

b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.

c. On information and belief, Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) – which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs and states that "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'"

d. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.

e. APF's Treatment Options: A Guide for People Living with Pain, sponsored by Cephalon and Purdue, counseled patients that opioids "give [pain patients] a quality of life we deserve." This publication is still available online.

f. On information and belief, Endo's NIPC website *painknowledge.com* claimed that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy.

g. On information and belief, Janssen sponsored, funded, and edited a website, *Let's Talk Pain*, in 2009, which featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function."

h. Purdue sponsored the development and distribution of APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients." The Policymaker's Guide is still available online today.

i. In a 2015 video on Forbes.com[54] discussing the introduction of Hysingla ER, Purdue's Vice President of Health Policy, J. David Haddox, talked

[54] Matthew Harper, *Why Supposedly Abuse-Proof Pills Won't Stop Opioid Overdose Deaths*, Forbes (Apr. 17, 2015), available at https://www.forbes.com/sites/matthewherper/2015/04/17/why-supposedly-abuse-proof-pills-pill-wont-stop-opioid-overdose-deaths/#6a4e41f06ce1 (last accessed December 20, 2017).

about the importance of opioids, including Purdue's opioids, to chronic pain patients' "quality of life," and complained that CDC statistics do not take into account that patients could be driven to suicide without pain relief.

183. The above claims find no support in the scientific literature. The FDA and other federal agencies have made this clear for years. Most recently, the 2016 CDC Guideline approved by the FDA concluded that "there is no good evidence that opioids improve pain or function with long-term use, and . . . complete relief of pain is unlikely." (emphasis added). The CDC reinforced this conclusion throughout its 2016 Guideline:

a. "No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later . . . ."

b. "Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy."

c. "[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."

184. The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations." As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

185. The 2016 CDC Guideline was not the first time a federal agency repudiated the Manufacturer Defendants' claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis that "[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side

effects patients may experience … results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[55] And upon information and belief, in 2008 the FDA sent a warning letter to an opioid manufacturer, making it publicly clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

186. The Manufacturer Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. For example, the Manufacturer Defendants frequently contrasted the lack of a ceiling dosage for opioids with the risks of a competing class of analgesics: over-the-counter nonsteroidal anti-inflammatories (or NSAIDs). The Manufacturer Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from opioids.[56] The Manufacturer Defendants have overstated the number of deaths from NSAIDS and have prominently featured the risks of NSAIDS, while minimizing or failing to mention the serious risks of opioids. Once again, these misrepresentations by the Manufacturer Defendants contravene pronouncements by and guidance from the FDA and CDC based on the

[55] Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at http://wayback.archive-it.org/7993/20170112063027/http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCcompanies/ucm259240.htm (last accessed December 20, 2017).

[56] *See, e.g.*, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (Endo) (describing massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids), available at http://www.painmedicinenews.com/download/BtoB_Opana_WM.pdf (last accessed December 19, 2017).

scientific evidence. For example, the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

187. Purdue misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours – a fact that Purdue has known at all times relevant to this action. Upon information and belief, Purdue's own research shows that OxyContin wears off in under six hours in one quarter of patients, and it wears off in under 10 hours in more than half of patients. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in 2008 that a "substantial proportion" of chronic pain patients taking OxyContin experience it. This not only renders Purdue's promise of 12 hours of relief false and deceptive; it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

188. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA expressly limited their use to the treatment of cancer pain in opioid tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for, or has been shown to be safe or effective for, chronic pain. Indeed, the FDA prohibited Cephalon from marketing Actiq for anything

but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm.

189. Despite this, on information and belief, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe.[57] As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain.

190. Cephalon's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses. For example:

a. Cephalon paid to have a CME it sponsored, Opioid-Based Management of Persistent and Breakthrough Pain, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "[c]linically, broad classification of pain syndromes as either cancer- or non-cancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain.

b. Upon information and belief, Cephalon's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.

c. In December 2011, Cephalon widely disseminated a journal supplement entitled "Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)" to Anesthesiology News, Clinical Oncology News, and Pain Medicine News – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain" – and not just cancer pain.

[57] *See* Press Release, U.S. Dep't of Justice, *Biopharmaceutical Company, Cephalon, to Pay $425 million & Enter Plea To Resolve Allegations of Off-Label Marketing* (Sept. 29, 2008), available at https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html (last accessed December 21, 2017).

191. The Manufacturer Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and misleading. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The Manufacturer Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on the medical evidence that conclusively expose the known falsity of the Manufacturer Defendants' misrepresentations.

192. On information and belief, the Manufacturer Defendants coordinated their messaging through national and regional sales and speaker trainings and coordinated advertisements and marketing materials.

193. Moreover, at all times relevant to this Complaint, the Manufacturer Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, the Manufacturer Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. The Manufacturer Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity

of the Manufacturer Defendants' false and misleading statements about the risks and benefits of long-term opioid use for chronic pain.

194. Finally, the Manufacturer Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. The Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The lack of support for the Manufacturer Defendants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions, nor could it have been detected by the Tribe.

195. The Manufacturer Defendants' efforts to artificially increase the number of opioid prescriptions directly and predictably caused a corresponding increase in opioid abuse. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses."[58] Many abusers start with legitimate prescriptions. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "[t]o reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."[59] Accordingly, the Manufacturer Defendants' false and misleading statements directly caused the current opioid epidemic.

[58] Rose A Rudd, et al., *Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014*, Morbidity and Mortality Wkly Rep. (Jan. 1, 2016), available at https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm (last accessed December 20, 2017).

[59] *Id.*

E. Manufacturer Defendants Failed to Effectively Communicate with Physicians and Patients about the Proper Use and the Abuse and Addiction Risks Associated with Their Brand and Generic Opioid Products

196. Manufacturer Defendants failed to effectively and adequately communicate the warnings that existed in the labels of their products to physicians, healthcare providers and the medical community. To ensure medical providers were aware of the risks and appropriate uses of prescription opioid narcotics, they owed a duty to effectively communicate clinically relevant information and warnings from their name-brand and generic prescription opioid products regarding these adverse health risks to ensure their proper and appropriate use.

197. Manufacturer Defendants knew that through years of misstatements and misrepresentations and other wrongful marketing had reversed the previous understanding among doctors, healthcare providers and the medical community that prescription opioids were intended only for limited uses and were highly addictive and subject to abuse, and that they no longer understood the proper uses for their drugs and their associated abuse and addiction risks. Manufacturer Defendants, therefore, breached their duty to ensure that the that the warning language and other information from their name-brand and generic prescription opioid product labels were effectively communicated to doctors, healthcare providers and the medical community through means of communication that did not require information or warnings different from the information and warnings in the approved FDA label, and did not require permission or assistance from the FDA. Such means included sending doctors and healthcare providers letters ("Dear Doctor" letters) that did not contain additional or substantial new warning information, but which highlighted and explained the products' warnings and other

information consistent with the product. Such letters can be appropriate to convey "important safety concern[s]," such as "clinically important new information about a known adverse reaction." Manufacturer Defendants had many other means of communication available to them to communicate the proper use and abuse and addition risks associated with their name-brand and generic opioid products, including through CME programs, speakers bureaus, thought leaders, patient advocacy groups and through the other branded and unbranded marketing techniques that had been developed, all as described herein.[60]

198. Manufacturer Defendants could have complied with both their Idaho statutory and tort law duties including to prevent foreseeable harms, and their requirements under federal law. These statutory and tort claims rest on traditional state-law principles that parallel federal safety requirements but do not exist solely by virtue of the FDA laws and regulations. Manufacturer Defendants could satisfy their state law duty by taking actions that comport with federal law.

199. Manufacturer Defendants had financial incentives to neither communicate or amplify a message about the dangers of prescription opioids, nor highlight clinically relevant data or information about their adverse health effects, because Manufacturer Defendants profited greatly from the sale of their prescription opioid products. Manufacturers of generic opioid products, in particular, depended on volume sales of their generic opioid products to increase their revenue and profits from their sales, and so were especially incentivized to market and sell their generic opioid products as widely as

[60] FDA, *Guidance for Industry: Dear Health Care Provider Letters* 3-4 (Jan. 2014), http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm233769.pdf (non-binding guidance).

possible. Thus, rather than act in accordance with their duties, Manufacturer Defendants aggressively marketed their opioid products to doctors and other healthcare providers, pharmacies, drug distributors, prescription benefit managers, formularies, insurance companies, and other third parties to increase the volume and their own share among of the name-brand and generic prescription opioid market.

200. Manufacturer Defendants knew or should have known that their failure to adequately communicate, highlight, and explain the warnings, labeling, and other information concerning prescription opioids, such as safety concerns and other information about proper use and adverse health consequences, would harm the Tribe and its citizens.

F. The Tribe Was Harmed by Manufacturer Defendants' Name-Brand Prescription Opioids and Their Generic Equivalents as a Result of Defendants' Wrongful Marketing Conduct

201. The Manufacturer Defendants' wrongful marketing efforts and techniques regarding branded and non-branded (generic) prescription opioids alleged herein increased the sale of prescription opioids by convincing doctors that prescription opioids could safely be used outside their indicated use and that the risk of addiction from prolonged use was rare and easily reversible.

202. When doctors were convinced through Manufacturer Defendants' wrongful marketing efforts and techniques regarding branded and non-branded prescription opioids alleged herein, to prescribe such Manufacturer Defendant's name brand prescription opioid, a pharmacist may, with the doctor's or patient's consent, substitute a generic equivalent of the name-brand opioid in full accord with Idaho state law. Many insurance companies will only pay for the generic equivalent, so a patient often consents to the substitution of a generic equivalent for the name-brand drug. Consequently, even though

the doctor may have prescribed a name-brand opioid, the prescription for that product often is filled with a generic equivalent by the pharmacist.

203. The Manufacturer Defendants knew, or it was reasonably foreseeable, that their wrongful marketing efforts and techniques regarding branded and non-branded prescription opioids alleged herein would lead in many instances to the substitution and sale of a generic equivalent for a name-brand prescription opioid by the pharmacist.

204. Those Manufacturer Defendants that manufactured and sold generic prescription opioids in addition to name-brand prescription opioids knew and intended their wrongful marketing conduct alleged herein would increase the sales and profits of both their name-brand and generic prescription opioids.

205. As a result of Manufacturer Defendants' wrongful conduct in marketing prescription opioids as alleged herein, including the sale of both name-brand prescription opioids and, where applicable, their generic equivalents, the Tribe suffered great harm and injury and continues to suffer great harm and injury.

G. All Defendants Created an Illicit Market for Opioids

206. In addition to the allegations above, all Defendants played a role in the creation of an illicit market for name-brand and generic prescription opioids, further fueling the opioid epidemic.

207. Defendants' distribution of opioids was driven by national policies, coordination, plans, and procedures that were the same in Idaho as they were across the country. Defendants worked together in an illicit enterprise, engaging in conduct that was not only illegal, but in certain respects anti-competitive, with the common purpose and achievement of vastly increasing their respective profits and revenues by exponentially expanding a market that the law intended to restrict. At all relevant times, Defendants

were in possession of national, regional, state, and local prescriber, patient, distributor and pharmacy-level data that allowed them to track prescribing, distribution and sales patterns over time. Defendants utilized this data to further their distribution scheme and to ensure the largest possible financial return.

208. Each participant in the supply chain shares the responsibility for controlling the availability of prescription opioids. Opioid "diversion" occurs whenever the supply chain of prescription opioids is broken, allowing drugs to be transferred from a legitimate channel of distribution or use to an illegitimate channel of distribution or use.

209. Diversion can occur at any point in the opioid supply chain.

210. For example, diversion can occur at the wholesale level of distribution when distributors allow opioids to be lost or stolen in transit, or when distributors fill suspicious orders of opioids from buyers, retailers, or prescribers. Suspicious orders include orders of unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern, and/or orders of unusual frequency.

211. Diversion can occur at pharmacies or retailers when a pharmacist fills a prescription despite having reason to believe it was not issued for a legitimate medical purpose or not in the usual course of practice. Some of the signs that a prescription may have been issued for an illegitimate medical purpose include when the patient seeks to fill multiple prescriptions from different doctors (known as doctor shopping), when they travel great distances between the doctor or their residence and the pharmacy to get the prescription filled, when they present multiple prescriptions for the largest dose of more than one controlled substance, or when there are other "red flags" surrounding the

transaction. These red flags should trigger closer scrutiny of the prescriptions by the pharmacy and lead to a decision that the patient is not seeking the medication to treat a legitimate medical condition.

212. Diversion occurs through the use of stolen or forged prescriptions or the sale of opioids without prescriptions, including patients seeking prescription opioids under false pretenses. Opioids can also be diverted when stolen by employees or others.

213. Opioid diversion occurs at an alarming rate in the United States.

214. Each participant in the supply chain, including each Defendant, has a common law duty to prevent diversion by using reasonable care under the circumstances. This includes a duty not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative conduct and thereafter realizes or should realize that such conduct has created an unreasonable risk of harm to another is under a duty to exercise reasonable care to prevent the threatened harm.

215. In addition to their common law duties, Defendants are subject to the statutory requirements of the Controlled Substances Act, 21 U.S.C. § 801 et seq. (the "CSA"), and its implementing regulations. Congress passed the CSA partly out of a concern about "the widespread diversion of [controlled substances] out of legitimate channels into the illegal market." H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572.

216. Defendants' repeated and prolific violations of these requirements show that they have acted with willful disregard for the Tribe, tribal communities, and the people therein.

217. The CSA imposes a legal framework for the distribution and dispensing of controlled substances. This framework acts as a system of checks and balances from

the manufacturing level through delivery of the controlled substance to the patient or ultimate user.

218. Every person or entity that manufactures, distributes, or dispenses opioids must obtain a registration with the DEA. Registrants at every level of the supply chain must fulfill their obligations under the CSA.

219. All opioid distributors are required to maintain effective controls against opioid diversion. They are required to create and use a system to identify and report to law enforcement downstream suspicious orders of controlled substances, such as orders of unusually large size, orders that are disproportionate, orders that deviate from a normal pattern, and/or orders of unusual frequency. To comply with these requirements, distributors must know their customers, must conduct due diligence, must report suspicious orders, and must terminate orders if there are indications of diversion.

220. Under the CSA, anyone authorized to handle controlled substances must track shipments. The DEA's Automation of Reports and Consolidation Orders System ("ARCOS") is an automated drug reporting system that records and monitors the flow of Schedule II controlled substances from the point of manufacture through distribution to the point of sale. ARCOS accumulates data on distributors' controlled substances and transactions, which are then used to identify diversion. Each person or entity registered to distribute ARCOS reportable controlled substances, including opioids, must report each acquisition and distribution transaction to the DEA. *See* 21 U.S.C. § 827; 21 C.F.R. § 1304.33. Each registrant must also maintain a complete, accurate, and current record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of.

221. Each registrant must also comply with the security requirements to prevent diversion set forth in 21 C.F.R. § 1301.71.

1. The Distributor Defendants Throughout the Supply Chain Deliberately Disregarded Their Duties to Maintain Effective Controls to Identify, Report, and Take Steps to Halt Suspicious Orders or Otherwise Act to Prevent Diversion

222. The DEA has provided guidance to distributors on how to combat opioid diversion. On information and belief, since 2006 the DEA has conducted one-on-one briefings with distributors regarding downstream customer sales, due diligence, and regulatory responsibilities. On information and belief, the DEA also provides distributors with data on controlled substance distribution patterns and trends, including data on the volume and frequency of orders and the percentage of controlled versus non-controlled purchases. On information and belief, the DEA has also hosted conferences for opioid distributors and has participated in numerous meetings and events with trade associations.

223. On September 27, 2006, and December 27, 2007, the DEA Office of Diversion Control sent letters to all registered distributors providing guidance on suspicious order monitoring and the responsibilities and obligations of registrants to prevent diversion.

224. As part of the legal obligation to maintain effective controls against diversion, the distributor is required to exercise due care in confirming the legitimacy of each and every order prior to filling. Circumstances that could be indicative of diversion include ordering excessive quantities of a limited variety of controlled substances while ordering few if any other drugs; ordering a disproportionate amount of controlled substances versus non-controlled prescription drugs; ordering excessive quantities of a

limited variety of controlled substances in combination with lifestyle drugs; and ordering the same controlled substance from multiple distributors.

225. Through their public statements, marketing, and advertising, each participant in the supply chain of opioid distribution is responsible to prevent diversion of prescription opioids into the illegal market by monitoring and reporting suspicious activity. Diversion can occur at any point in the opioid supply chain when prescriptions are filled for any reason other than a legitimate medical purpose.

226. Diversion can occur at pharmacies whenever a pharmacy fills a prescription despite having reason to believe it was not issued for a legitimate medical purpose or not in the usual course of practice. Diversion can also occur through the use of stolen of forged prescriptions at pharmacies, or the sale of opioids without prescriptions, including patients seeking prescriptions under false pretense.

227. Each Distributer Defendant in the supply chain had knowledge and/or notice of the damages caused and continuing to be caused and continuing to be caused by their conduct and could and should have taken measures, including but not limited to those set forth herein, to curb expansion of opioid use and to prevent or minimize diversion and the cascading damages caused by their wrongful conduct.

228. Suspicious orders must be reported when discovered. Registrants must perform an independent analysis of a suspicious order prior to the sale to determine if the controlled substances would likely be diverted. Filing a suspicious order and then completing the sale does not absolve the registrant from legal responsibility.

229. The Distributor Defendants' actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids.

230. On information and belief, the Distributor Defendants' own industry group, the Healthcare Distribution Management Association, published Industry Compliance Guidelines titled "Reporting Suspicious Orders and Preventing Diversion of Controlled Substances," emphasizing the critical role of each member of the supply chain in distributing controlled substances. These industry guidelines stated: "At the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers."

231. Opioid distributors have admitted to the magnitude of the problem and, at least superficially, have acknowledged their legal responsibilities to prevent diversion. They have made statements assuring the public they are supposedly undertaking a duty to curb the opioid epidemic.

232. These assurances, on their face, of identifying and eliminating criminal activity and curbing the opioid epidemic, create a duty for the Distributor Defendants to take reasonable measures to do just that.

233. Despite their duties to prevent diversion, the Distributor Defendants have knowingly or negligently allowed diversion.[61] The DEA has repeatedly taken action to

[61] Scott Higham and Lenny Bernstein, *The Drug Industry's Triumph Over the DEA*, Wash. Post (Oct. 15, 2017), available at https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm_term=.75e86f3574d3 (last accessed December 21, 2017); Lenny Bernstein, David S. Fallis, and Scott Higham, *How drugs intended for patients ended up in the hands of illegal users: 'No one was doing their job,'* Wash. Post (Oct. 22, 2016), available at https://www.washingtonpost.com/investigations/how-drugs-i

attempt to force compliance, including 178 registrant actions between 2008 and 2012, 76 orders to show cause issued by the Office of Administrative Law Judges, and 41 actions involving immediate suspension orders.[62] The Distributor Defendants' wrongful conduct and inaction have resulted in numerous civil fines and other penalties, including:

a. In a 2017 Administrative Memorandum of Agreement between McKesson and the DEA, McKesson admitted that it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters." McKesson was fined $150,000,000.[63]

b. McKesson has a history of repeatedly failing to perform its duties. In May 2008, McKesson entered into a settlement with the DEA on claims that McKesson failed to maintain effective controls against diversion of controlled substances. McKesson allegedly failed to report suspicious orders from rogue internet pharmacies around the country, resulting in millions of doses of controlled substances being diverted. McKesson's system for detecting "suspicious orders" from pharmacies was so ineffective and dysfunctional that at one of its facilities in Colorado between 2008 and 2013, filled more than 1.6 million orders, for tens of millions of controlled substances, but it reported just 16 orders as suspicious, all from a single consumer.

c. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Auburn, Washington, for failure to maintain effective controls against diversion.

d. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Lakeland, Florida, for failure to maintain effective controls against diversion.

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ntended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?tid=graphics-story&utm_term=.4f439ef106a8 (last accessed December 21, 2017).

[62] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), available at https://oig.justice.gov/reports/2014/e1403.pdf (last accessed January 8, 2018).

[63] Administrative Memorandum of Agreement between the U.S. Dep't of Justice, the Drug Enf't Admin., and the McKesson Corp. (Jan. 17, 2017), available at https://www.justice.gov/opa/press-release/file/928476/download (last accessed December 21, 2017).

e. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Swedesboro, New Jersey, for failure to maintain effective controls against diversion.

f. On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Stafford, Texas, for failure to maintain effective controls against diversion.

g. In 2008, Cardinal paid a $34 million penalty to settle allegations about opioid diversion taking place at seven of its warehouses in the United States.[64]

h. On February 2, 2012, the DEA issued another Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Lakeland, Florida, for failure to maintain effective controls against diversion.

i. In 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states.

j. In December 2016, the Department of Justice announced a multi-million dollar settlement with Cardinal for violations of the Controlled Substances Act.[65]

k. On information and belief, in connection with the investigations of Cardinal, the DEA uncovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to a particular pharmacy in Wisconsin that was suspected of opioid diversion. Cardinal did nothing to notify the DEA or cut off the supply of drugs to the suspect pharmacy. Cardinal did just the opposite, pumping up opioid shipments to the pharmacy to almost 2,000,000 doses of oxycodone in one year, while other comparable pharmacies were receiving approximately 69,000 doses/year.

[64] Lenny Bernstein and Scott Higham, *Cardinal Health fined $44 million for opioid reporting violations*, Wash. Post (Jan. 11, 2017), available at https://www.washingtonpost.com/national/health-science/cardinal-health-fined-44-million-for-opioid-reporting-violations/2017/01/11/4f217c44-d82c-11e6-9a36-1d296534b31e_story.html?utm_term=.0c8e17245e66 (last accessed December 21, 2017).

[65] Press Release, United States Dep't of Justice, *Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act*, Dec. 23, 2016, available at https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act (last accessed December 21, 2017).

l. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies.

m. In 2012, AmerisourceBergen was implicated for failing to protect against diversion of controlled substances into non-medically necessary channels.

234. Although distributors have been penalized by law enforcement authorities, these penalties have not changed their conduct. They pay fines as a cost of doing business in an industry that generates billions of dollars in revenue and profit.

235. The Distributor Defendants' failure to prevent the foreseeable injuries from opioid diversion created an enormous black market for prescription opioids, which extended to the Tribe and its members. Each Distributor Defendant knew or should have known that the opioids reaching the Tribe were not being consumed for medical purposes and that the amount of opioids flowing to the Tribe was far in excess of what could be consumed for medically necessary purposes.

236. The Distributor Defendants negligently or intentionally failed to adequately control their supply lines to prevent diversion. A reasonably prudent distributor of Schedule II controlled substances would have anticipated the danger of opioid diversion and protected against it by, for example: taking greater care in hiring, training, and supervising employees; providing greater oversight, security, and control of supply channels; looking more closely at the pharmacists and doctors who were purchasing large quantities of commonly abused opioids in amounts greater than the populations in those areas would warrant; investigating demographic or epidemiological facts concerning the increasing demand for narcotic painkillers in and around the Tribe; providing information to pharmacies and retailers about opioid diversion; and in general,

simply following applicable statutes, regulations, professional standards, and guidance from government agencies and using common sense.

237. On information and belief, the Distributor Defendants made little to no effort to visit the pharmacies servicing the areas around the Tribe to perform due diligence inspections to ensure that the controlled substances the Distributor Defendants had furnished were not being diverted to illegal uses.

238. On information and belief, the compensation the Distributor Defendants provided to certain of their employees was affected, in part, by the volume of their sales of opioids to pharmacies and other facilities servicing the areas around the Tribe, thus improperly creating incentives that contributed to and exacerbated opioid diversion and the resulting epidemic of opioid abuse.

239. It was reasonably foreseeable to the Distributor Defendants that their conduct in flooding the market in and around the Tribe with highly addictive opioids would allow opioids to fall into the hands of children, addicts, criminals, and other unintended users.

240. It is reasonably foreseeable to the Distributor Defendants that, when unintended users gain access to opioids, tragic preventable injuries will result, including addiction, overdoses, and death. It is also reasonably foreseeable that many of these injuries will be suffered by tribal members, and that the costs of these injuries will be borne by the Tribe, as well as the surrounding community served by the Tribe.

241. The Distributor Defendants knew or should have known that the opioids being diverted from their supply chains would contribute to the opioid epidemic faced by the Tribe, and would create access to opioids by unauthorized users, which, in turn,

perpetuates the cycle of addiction, demand, illegal transactions, economic ruin, and human tragedy.

242. The Distributor Defendants were aware of widespread prescription opioid abuse in and around the Tribe, but, on information and belief, they nevertheless persisted in a pattern of distributing commonly abused and diverted opioids in geographic areas-and in such quantities, and with such frequency that they knew or should have known these commonly abused controlled substances were not being prescribed and consumed for legitimate medical purposes.

243. The use of opioids by tribal members who were addicted or who did not have a medically necessary purpose for use could not occur without the knowing cooperation and assistance of the Distributor Defendants. If the Distributor Defendants adhered to effective controls to guard against diversion, the Tribe and its members would have avoided significant injury.

244. The Distributor Defendants made substantial profits over the years based on the diversion of opioids into the Tribe. The Distributor Defendants knew that the Tribe would be unjustly forced to bear the costs of these injuries and damages.

245. The Distributor Defendants' intentional distribution of excessive amounts of prescription opioids to relatively small communities primarily serving Tribe members showed an intentional or reckless disregard for the safety of the Tribe and its members. Their conduct poses a continuing threat to the health, safety, and welfare of the Tribe.

246. The federal and state laws at issue here are public safety laws.

247. The Distributor Defendants' violations constitute prima facie evidence of negligence under state law.

2. National Retail Pharmacies Were on Notice of and Contributed to Illegal Diversion of Prescription Opioids

248. National retail pharmacy chains earned enormous profits by flooding the country with prescription opioids. They were keenly aware of the oversupply of prescription opioids through the extensive data and information they developed and maintained as both distributors and dispensaries. Yet, instead of taking any meaningful action to stem the flow of opioids into communities, they continued to participate in the oversupply and profit from it.

249. Each of the National Retail Pharmacies does substantial business throughout the United States. This business includes the distribution and dispensing of prescription opioids.

250. Statewide ARCOS data confirms that the National Retail Pharmacies distributed and dispensed substantial quantities of prescription opioids, including fentanyl, hydrocodone and oxycodone in Idaho. In addition, they distributed and dispensed substantial quantities of prescription opioids in other states, and these drugs were diverted from these other states to Idaho. The National Retail Pharmacies failed to take meaningful action to stop this diversion despite their knowledge of it, and contributed substantially to the diversion problem.

251. The National Retail Pharmacies developed and maintained extensive data on opioids they distributed and dispensed. Through this data, National Retail Pharmacies had direct knowledge of patterns and instances of improper distribution, prescribing, and use of prescription opioids in communities through the country, and in Idaho in particular. They used the data to evaluate their own sales activities and workforce. On information and belief, the National Retail Pharmacies also provided Defendant with data regarding,

inter alia, individual doctors in exchange for rebates or other forms of consideration. The National Retail Pharmacies' data is a valuable resource that they could have used to help stop diversion but failed to do so.

252. Each participant in the supply chain of opioid distribution, including the National Retail Pharmacies is responsible for preventing diversion of prescription opioids into the illegal market by, among other things, monitoring, and reporting suspicious activity.

253. The National Retail Pharmacies, like manufacturers and other distributors, are registrants under the CSA. 221 C.F.R.§1301.11. Under the CSA, pharmacy registrants are required to "provide effective controls and procedures to guard against theft and diversion of controlled substances." See 21 C.F.R. §1301.71(a). In addition, 21 C.F.R. §1306.04(a) states, "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacists who fills the prescription." Because pharmacies themselves are registrants under the CSA, the duty to prevent diversion lies with the pharmacy entity, not the individual pharmacists alone.

254. The DEA, among others, has provided extensive guidance to pharmacies concerning their duties to the public. The guidance advises pharmacies how to identify suspicious orders and other evidence of diversion. The guidance teaches pharmacies how to identify red flags, which indicate to the pharmacy that there may be a problem with the legitimacy of a prescription presented by a patient. The guidance also tells pharmacies how to resolve the red flags and what to do if the red flags are unresolvable.

255. Suspicious pharmacy orders include orders of unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern and/or orders of unusual frequency and duration, among others.

256. Additional types of suspicious orders include: prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities) for controlled substances compared to other practitioners in the area; prescriptions which should last for a month in legitimate use, but are being refilled on a shorter basis; prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time; prescriptions that look "too good" or where the prescriber's handwriting is too legible; prescriptions with quantities or dosage that differ from usual medical usage; prescriptions that do not comply with standard abbreviations and/or contain no abbreviations; photocopied prescriptions; or prescriptions containing different handwritings. Most of the time, these attributes are not difficult to detect or recognize; they should be easily recognizable by pharmacies.

257. Suspicious pharmacy orders are red flags for, if not direct evidence of, diversion.

258. Other signs of diversion can be observed through data gathered, consolidated, and analyzed by the National Retail Pharmacies themselves. That data allows them to observe patterns or instances of dispensing that are potentially suspicious, of oversupply in particular stores or geographic areas, or of prescribers or facilities that seem to engage in improper prescribing.

259. According to industry stands, if a pharmacy finds evidence of prescription diversion, the local Board of Pharmacy and DEA must be contacted.

260. Despite their legal obligations as registrants under the CSA, the National Retail Pharmacies allowed widespread diversion to occur – and they did so knowingly.

261. Performance metrics and prescription quota adopted by the National Retail Pharmacies for their retail stores contributed to their failure. Under CVS's Metrics System, for example, pharmacies are directed to meet high goals that make it difficult, if not impossible, to comply with applicable laws and regulations. There is no measurement for pharmacy accuracy or customer safety. Moreover, the bonuses for pharmacists are calculated, in part, on how many prescriptions that pharmacist fills within a year. The result is both deeply troubling and entirely predictable: opioids flowed out of the National Retail Pharmacies and into communities throughout the country. The policies remained in place even as the epidemic raged.

262. Upon information and belief, this problem was compounded by the Pharmacies' failure to adequately train their pharmacists and pharmacy technicians on how to properly and adequately handle prescriptions for opioid painkillers, including what constitutes a proper inquiry into whether a prescription is legitimate, whether a prescription is likely for a condition for which the FDA has approved treatments with opioids, and what measures and/or actions to take when a prescription is identified as phony, false, forged, or otherwise illegal, or when suspicious circumstances are present, including when prescriptions are procured and pills supplied for the purpose of illegal diversion and drug trafficking.

263. Upon information and belief, the National Retail Pharmacies also failed to use data available to them to identify doctors who were writing suspicious numbers of prescriptions and/or prescriptions of suspicious amounts of opioids, or to adequately use data available to them to do statistical analysis to prevent the filling of prescriptions that were illegally diverted or otherwise contributed to the opioid crisis.

264. Upon information and belief, the National Retail Pharmacies failed to analyze: (a) the number of opioid prescriptions filled by individual pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; (c) the number of opioid prescriptions filled relative to other drugs; and (d) the increase in annual opioid sales relative to the increase in annual sales of other drugs.

265. Upon information and belief, the National Retail Pharmacies failed to conduct adequate internal or external audits of their opioid sales to identify patterns regarding prescriptions that should not have been filled and to create policies accordingly, or if they conducted such audits, they failed to take any meaningful action as a result.

266. Upon information and belief, the National Retail Pharmacies also failed to effectively respond to concerns raised by their own employees regarding inadequate policies and procedures regarding the filling of opioid prescriptions.

267. The National Retail Pharmacies clearly knew that an opioid epidemic existed as they considered and/or implemented changes to their security procedures to address retail outlet concerns regarding customers who were, may have been, or had the potential to become addicts.

268. The National Retail Pharmacies were, or should have been, fully aware that the quantity of opioids being distributed and dispensed by them was untenable, and

in many areas patently absurd; yet they did not take meaningful action to investigate or to ensure that they were complying with their duties and obligations under the law with regard to controlled substances.

269. The National Retail Pharmacies could and should have unilaterally taken action, and/or offered a program to third-party payers, which had the effect of: (a) limiting to 7 days the supply of opioids dispensed for certain acute prescriptions; (b) reducing the dispensing of stronger and extended release opioids; (c) enhancing pharmacists counseling for new opioid patients; (d) limiting the daily dosage of opioids dispensed based on the strength of the opioid; and (e) requiring the use of immediate-release formulations of opioids before extended-release opioids are dispensed.

3. Multiple Enforcement Actions Against the National Retail Pharmacies Confirms Their Compliance Failures

270. The National Retail Pharmacies have long been on notice of their failure to abide by state and federal law and regulations governing the distribution and dispensing of prescription opioids. Indeed, several of the National Retail Pharmacies have been repeatedly penalized for their illegal prescription opioid practices. Upon information and belief, based upon the widespread nature of these violations, these enforcement actions are the product of, and confirm, national policies and practices of the National Retail Pharmacies.

a. CVS

271. CVS is one of the largest companies in the world, with annual revenue of more than $150 billion. According to news reports, it manages medications for nearly 90 million customers at 9,700 retail locations.

272. CVS is a repeat offender and recidivist: the company has paid fines totaling over $40 million as the result of a series of investigations by the DEA and the United States Department of Justice ("DOJ"). It nonetheless treated these fines as the cost of doing business and has allowed its pharmacies to continue dispensing opioids in quantities significantly higher than any plausible medical need would require, and to continue violating its recordkeeping and dispensing obligations under the CSA.

273. As recently as July 2017, CVS entered into a $5 million settlement with the U.S. Attorney's Office for the Eastern District of California regarding allegations that its pharmacies failed to keep and maintain accurate records of Schedule II, III, IV and V controlled substances.[66] This fine was preceded by numerous others throughout the country.

274. In February 2016, CVS entered into an $8 million dollar settlement with the DEA "reflect[ing] the federal commitment to prevent the diversion of pharmaceutical drugs for illegal purposes."[67] According to the settlement agreement, CVS acknowledged that between 2008 and 2012 certain CVS pharmacy stores dispensed controlled substances, including oxycodone, fentanyl and hydrocodone, in a manner not fully consistent with their compliance obligations under the CSA and related regulations."[68]

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[66] Press Release, U.S. Dep't of Just., U.S. Attorney's Office E. Dist. of Cal., *CVS Pharmacy Inc. Pays $5M to Settle Alleged Violations of the Controlled Substance Act,* (July 11, 2017), https://www.justice.gov/usao-edca/pr/cvs-pharmacy-inc-pays-5m-settle-alleged-violations-controlled-substance-act.

[67] United States Attorney's Office District of Maryland, Press Release, *United States Reaches $8 Million Settlement Agreement with CVS for Unlawful Distribution of Controlled Substances* (Feb. 12, 2016), https://www.justice.gov/usao-md/pr/united-states-reaches-8-million-settlement-agreement-cvs-unlawfuldistribution-controlled

[68] *Id.*

This included "failing to comply with a pharmacist's liability to ensure the controlled substance prescriptions were issued for a legitimate medical purpose."[69]

275. In June 2016, CVS agreed to pay the DOJ $3.5 million to resolve allegations that 50 of its stores violated the CSA by filling forged prescriptions for controlled substances – mostly addictive painkillers - more than 500 times between 2011 and 2014.[70]

276. In September 2016, CVS entered into a $795,000 settlement with the Massachusetts Attorney General wherein CVS agreed to require pharmacy staff to access the state's prescription monitoring program website and review a patient's prescription history before dispensing certain opioid drugs.[71]

277. In October 2016, CVS paid $600,000 to settle allegations by the DOJ that stores in Connecticut failed to maintain proper records in accordance with the CSA.[72]

278. In August 2015, CVS entered into a $450,000 settlement with the U.S. Attorney's Office for the District of Rhode Island to resolve allegations that several of its Rhode Island stores violated the CSA by filling invalid prescriptions and maintaining

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[69] *Id.*

[70] Press Release, U.S. Dept't of Just., U.S Attorney's Office Dist. of Mass., *CVS to Pay $3.5 Million to Resolve Allegations that Pharmacists Filled Fake Prescriptions.*, (June 30, 2016), https://www.justice.gov/usao-ma/pr/cvs-pay-35-million-resolve-allegations-pharmacists-filled-fake-prescriptions.

[71] Dialynn Dwyer, *CVS Will Pay $795,000, Strengthen Policies Around Dispensing Opioids in Agreement with State*, Boston.com (Sept. 1, 2016), https://www.boston.com/news/local-news/2016/09/01/cvs-will-pay-795000-strengthen-policies-around-dispensing-opioids-in-agreement-with-state.

[72] Press Release, U.S. Dep't of Just., U.S. Attorney's Office Dist. of Conn., *CVS Pharmacy Pays $600,000 to Settle Controlled Substances Act Allegations,* (Oct. 20, 2016), https://www.justice.gov/usao-ct/pr/cvs-pharmacy-pays-60000-settle-controlled-substances-act-allegations.

deficient records. The United States alleged that CVS retail pharmacies in Rhode Island filled a number of forged prescriptions with invalid DEA numbers, and filled multiple prescriptions written by psychiatric nurse practitioners for hydrocodone, despite the fact that these practitioners were not legally permitted to prescribe that drug. Additionally, the government alleged that CVS had recordkeeping deficiencies.[73]

279. In May 2015, CVS agreed to pay a $22 million penalty following a DEA investigation that found that employees at two pharmacies in Sanford, Florida, had dispensed prescription opioids, "based on prescriptions that had not been issued for legitimate medical purposes by a health care provider acting in the usual course of professional practice. CVS also acknowledged that its retail pharmacies had a responsibility to dispense only those prescriptions that were issued on legitimate medical need."[74]

280. In September 2014, CVS agreed to pay $1.9 million in civil penalties to resolve allegations it filled prescriptions written by a doctor whose controlled-substance registration had expired.[75]

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[73] Press Release, U.S. Dep't of Just., U.S. Attorney's Office Dist. of R.I., Drug Diversion Claims Against CVS Health Corp. Resolved With $450,000 Civil Settlement, (Aug. 10, 2015), https://www.justice.gov/usao-ri/pr/drug-diversion-claims-against-cvs-health-corp-resolved-450000-civil-settlement.

[74] Press Release, U.S. Dep't of Just., U.S. Attorney's Office M. Dist. of Fla., United States Reaches $22 Million Settlement Agreement With CVS For Unlawful Distribution of Controlled Substances, (May 13, 2015), https://www.justice.gov/usao-mdfl/pr/united-states-reaches-22-million-settlement-agreement-cvs-unlawful-distribution.

[75] Patrick Danner, H-E-B, CVS Fined Over Prescriptions, San Antonio Express-News http://www.expressnews.com/business/local/article/H-E-BCVS-fined-over-prescriptions-5736554.php. (Las Updated Sept. 5, 2014, 8:00 PM).

281. In August 2013, CVS was fined $350,000 by the Oklahoma Pharmacy Board for improperly selling prescription narcotics in at least five locations in the Oklahoma City metropolitan area.[76]

282. Dating back to 2006, CVS retail pharmacies in Oklahoma and elsewhere intentionally violated the CSA by filling prescriptions signed by prescribers with invalid DEA registration numbers.[77]

b. Walgreens

283. Walgreens is the second-largest pharmacy store chain in the United States behind CVS, with annual revenue of more than $118 billion. According to its website, Walgreens operates more than 8,100 retail locations and filled 990 million prescriptions on a 30-day adjusted basis in fiscal 2017.

284. Walgreens also has been penalized for serious and flagrant violations of the CSA. Indeed, Walgreens agreed to the largest settlement in DEA history - $80 million – to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations of the CSA, including negligently allowing controlled substances such as oxycodone and other prescription opioids to be diverted for abuse and illegal black market sales.[78]

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[76] Andrew Knittle, *Oklahoma Pharmacy Board Stays Busy, Hands Out Massive Fines at Times,* NewsOK http://newsok.com/article/5415840. (Last Updated May 4, 2015, 5:00 PM).

[77] Press Release, U.S. Dep't. of Just., U.S. Attorney's Office W. Dist. of Okla., CVS to Pay $11 Million To Settle Civil Penalty Claims Involving Violations of Controlled Substances Act, (Apr. 3, 2013), http://www.justice.gov/usao-wdok/pr/cvd/pay-11-milion-settle-civil-penalty-claims-involving-violations-controlled.

[78] Press Release, U.S. Dep't of Just., U.S. Attorney's Office S. Dist. of Fla., *Walgreens Agrees to Pay A Record Settlement Of $80 Million For Civil Penalties*

285. The settlement resolved investigations into and allegations of CSA violations in Florida, New York, Michigan, and Colorado that resulted in the diversion of millions of opioids into illicit channels.

286. Walgreens' Florida operations at issue in this settlement highlight its egregious conduct regarding diversion of prescription opioids. Walgreens' Florida pharmacies each allegedly ordered more than one million dosage units of oxycodone in 2011 – more than ten times the average amount.[79]

287. Walgreens increased their orders over time, in some cases as much as 600% in the space of just two years, including, for example, supplying a town of 3,000 with 285,000 orders of oxycodone in a one-month period. Walgreens corporate officers turned a blind eye to these abuses. In fact, corporate attorneys at Walgreens suggested, in reviewing the legitimacy of prescriptions coming from pain clinics, that "if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance," underscoring Walgreens' attitude that profit outweighed compliance with the CSA or the health of communities.[80]

288. Defendant Walgreens' settlement with the DEA stemmed from the DEA's investigation into Walgreens' distribution center in Jupiter, Florida, which was responsible for significant opioid diversion in Florida. According to the Order to Show

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Under the Controlled Substances Act, (June 11, 2013), http://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-record-settlement-80-million-civil-penalties-under-controlled.

[79] Appendix B of Order to Show Cause and Immediate Suspension of Registration, *In the Matter of Walgreens Co.* (Drug Enf't Admin. Sept. 13, 2012), https://www.dea.gov/divisions/mia/2013/mia061113_appendixb.pdf.

[80] *Id.*

Cause, Defendant Walgreens' corporate headquarters pushed to increase the number of oxycodone sales to Walgreens' Florida pharmacies, and provided bonuses for pharmacy employees based on number of prescriptions filled at the pharmacy in an effort to increase oxycodone sales. In July 2010, Defendant Walgreens ranked all of its Florida stores by number of oxycodone prescriptions dispensed in June of that year, and found that the highest-ranking store in oxycodone sales sold almost 18 oxycodone prescriptions per day. All of these prescriptions were filled by the Jupiter Center.[81]

289. Walgreens has also settled with a number of state attorneys general, including West Virginia ($575,000) and Massachusetts ($200,000).[82]

290. The Massachusetts Attorney General's Medicaid Fraud Division found that, from 2010 through most of 2015, multiple Walgreens stores across the state failed to monitor the opioid use of some Medicaid patient who were considered high-risk.

291. In January 2017, an investigation by the Massachusetts Attorney General found that some Walgreens pharmacies failed to monitor patients' drug use patterns and didn't use sound professional judgement when dispensing opioids and other controlled substances – despite the context of soaring overdose deaths in Massachusetts. Walgreens agreed to pay $200,000 and follow certain procedures for dispensing opioids.[83]

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[81] *Id.*

[82] Felice J. Freyer, *Walgreens to Pay $200,000 Settlement for Lapses with Opioids,* APhA (Jan. 25, 2017), https://www.pharmacist.com/article/walgreens-pay-200000-settlement-lapses-opiods.

[83] *Id.*

c. Rite Aid

292. With approximately 4,600 stores in 31 states and the District of Columbia, Rite Aid is the largest drugstore chain on the East Coast and the third-largest in the United States, with annual revenue of more than $21 billion.

293. In 2009, as a result of a multi-jurisdictional investigation by the DOJ, Rite Aid and nine of its subsidiaries in eight states were fined $5 million in civil penalties for its violations of the CSA.[84]

294. The investigation revealed that from 2004 onwards, Rite Aid pharmacies across the country had a pattern of non-compliance with the requirements of the CSA and federal regulations that lead to the diversion of prescription opioids in an around the communities of the Rite Aid pharmacies that were investigated. Rite Aid also failed to notify the DEA of losses of controlled substances in violation of 21 USC 842(a)(5) and 21 C.F.R.1301.76(b).[85]

295. Numerous state and federal drug diversion prosecutions have occurred in which prescription opioid pills were procured from National Retail Pharmacies. The allegations in this Complaint do not attempt to identify all these prosecutions, and the information above is merely by way of example.

296. The litany of state and federal actions against the National Retail Pharmacies demonstrate that they routinely, and as a matter of standard operation

[84] Press Release, Dep't of Just., *Rite Aid Corporation and Subsidiaries Agree to Pay $5 Million in Civil Penalties to Resolve Violations in Eight States of the Controlled Substances Act,* U.S. Dep't of Just. (Jan. 12, 2009), https//www.justice.gov/opa/pr/rite-aid-corporation-and-subsidiaries-agree-pay-5-million-civil-penalties-resolve-violations.

[85] *Id.*

procedure, violated their legal obligations under the CSA and other laws and regulations that govern the distribution and dispensing of prescription opioids.

297. Throughout the country and in Idaho in particular, the National Retail Pharmacies were or should have been aware of numerous red flags of potential suspicious activity and diversion.

298. On information and belief, the National Retail Pharmacies knew or reasonably should have known about the disproportionate flow of opioids into Idaho and the operation of "pill mills" that generated opioid prescriptions that, by their quantity or nature, were red flags or if not direct evidence of illicit supply and diversion. Additional information was provided by news reports, and state and federal regulatory actions, including prosecutions of pill mills in the area.

299. On information and belief, the National Retail Pharmacies knew or reasonably should have known about the devastating consequences of the oversupply and diversion of prescription opioids, including spiking opioid overdose rates in Plaintiff's community.

300. On information and belief, because of (among other sources of information) regulatory and other actions taken against the National Retail Pharmacies directly, actions taken against others pertaining to prescription opioids obtained from their retail stores, complaints and information from employees and other agents, and the massive volume of opioid prescription drug sale data that they developed and monitored, the National Retail Pharmacies were well aware that their distribution and dispensing activities fell far short of legal requirements.

301. Having knowledge and/or notice of the damages that the National Retail Pharmacies' conduct had caused to Plaintiff and others, they still failed to take other steps to help curb the damages already incurred by Plaintiff. Such steps the National Retail Pharmacies' could have taken included, among other things: (a) Donating medication disposal units to community police departments across the country to ensure unused opioid painkillers are disposed of properly rather than taken by individuals to who the prescription was not written or otherwise diverted or abused; (b) Implementing a program that consists of providing counseling to patients who are receiving an opioid prescription for the first time, such as by discussing the risks of dependence and addiction associated with opioid use and discussing and answering any questions or concerns such patients may have; and (c) Running public education campaigns to share facts about opioid abuse.

302. The National Retail Pharmacies' actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have contributed significantly to the opioid crisis by enabling, and failing to prevent, the diversion of opioids.

4. The Manufacturer Defendants Negligently Failed to Control the Flow of Opioids to the Tribe Through Illicit Channels

303. The same legal duties to prevent diversion, and to monitor, report, and prevent suspicious orders of prescriptions opioids that were incumbent upon the Distributor Defendants were also legally required of the Manufacturer Defendants under federal law.

304. Like the Distributor Defendants, the Manufacturer Defendants are required to design and operate a system to detect suspicious orders, and to report such

orders to law enforcement. (*See* 21 C.F.R. § 1301.74(b); 21 U.S.C. § 823). The Manufacturer Defendants have not done so.

305. On information and belief, for over a decade the Manufacturer Defendants have been able to track the distribution and prescribing of their opioids down to the retail and prescriber level. Thus, the Manufacturer Defendants had actual knowledge of the prescribing practices of doctors, including red flags indicating diversion. The Manufacturer Defendants did not report those red flags, nor did they cease marketing to those doctors. Like the Distributor Defendants, the Manufacturer Defendants breached their duties under federal and state law.

306. The Manufacturer Defendants had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The Manufacturer Defendants engaged in the practice of paying "chargebacks" to opioid distributors. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer's product at a price below a specified rate. After a distributor sells a manufacturer's product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, the Manufacturer Defendants knew – the volume, frequency, and pattern of opioid orders being placed and filled. The Manufacturer Defendants built receipt of this information into the payment structure for the opioids provided to the opioid distributors.

307. The Department of Justice has recently confirmed the suspicious order obligations clearly imposed by federal law (21 C.F.R. § 1301.74(b); 21 U.S.C. §

823(a)(1)), fining Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.[86] Among the allegations resolved by the settlement, the government charged "Mallinckrodt failed to design and implement an effective system to detect and report suspicious orders for controlled substances – orders that are unusual in their frequency, size, or other patterns. . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders."[87] Mallinckrodt agreed that its "system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007."[88]

308. Purdue also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Through its extensive network of sales representatives, Purdue had and continues to have knowledge of the prescribing practices of thousands of doctors and could identify doctors who displayed red flags for diversion, such as those whose waiting rooms were overcrowded, whose parking lots had numerous out-of-state vehicles, and whose patients seemed young and healthy or homeless. Using this information, Purdue has maintained a database since

[86] *See* Press Release, U.S. Dep't of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), available at https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious- orders.

[87] *Id*. (internal quotation omitted).

[88] 2017 Mallinckrodt MOA at p. 2-3.

2002 of doctors suspected of inappropriately prescribing its drugs.[89] Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin – the same OxyContin that Purdue had promoted as less addictive – in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the *Los Angeles Times*,[90] Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take action – even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report until years after law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin tablets, which Purdue's district manager described internally as "an organized drug ring." In doing so, Purdue protected its own profits at the expense of public health and safety.

309. In 2016, the NY AG found that, between January 1, 2008 and March 7, 2015, Purdue's sales representatives, at various times, failed to timely report suspicious prescribing and continued to detail those prescribers even after they were placed on a "no-call" list.[91]

[89] Scott Glover and Lisa Girion, *OxyContin maker closely guards its list of suspect doctors*, L.A. Times (August 11, 2013), available at http://articles.latimes.com/2013/aug/11/local/la-me-rx-purdue-20130811 (last accessed December 20, 2017).

[90] Harriet Ryan et al., *More than 1 million OxyContin pills ended up in the hands of criminal and addicts. What the drugmaker knew*, L.A. Times (July 10, 2016), available at http://www.latimes.com/projects/la-me-oxycontin-part2/ (last accessed December 20, 2017).

[91] *See* NY Purdue Settlement, at 6-7, available at https://ag.ny.gov/pdfs/Purdue-AOD-Executed.pdf (last accessed December 20, 2017).

310. As Dr. Mitchell Katz, director of the Los Angeles County Department of Health Services, said in a *Los Angeles Times* article, "Any drug company that has information about physicians potentially engaged in illegal prescribing or prescribing that is endangering people's lives has a responsibility to report it."[92] The NY AG's settlement with Purdue specifically cited the company for failing to adequately address suspicious prescribing. Yet, on information and belief, Purdue continues to profit from the prescriptions of such prolific prescribers.

311. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the NY AG found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list. The NY AG also found that, in certain cases where Endo's sales representatives detailed prescribers who were convicted of illegal prescribing of opioids, those representatives could have recognized potential signs of diversion and reported those prescribers but failed to do so.

312. On information and belief, the other Manufacturer Defendants have engaged in similar conduct in violation of their responsibilities to prevent diversion.

[92] Scott Glover and Lisa Girion, *OxyContin maker closely guards its list of suspect doctors*, L.A. Times (August 11, 2013), available at http://articles.latimes.com/2013/aug/11/local/la-me-rx-purdue-20130811 (last accessed December 20, 2017).

313. The Manufacturer Defendants' actions and omission in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids into the Tribe's community.

H. The Opioids the Defendants Sold Migrated Into Other Jurisdictions, Causing an Interstate Crisis

314. As the demand for prescription opioids grew, fueled by their potency and purity, interstate commerce flourished: opioids moved from areas of high supply to areas of high demand, traveling across state, city, county and tribal lines in a variety of ways.

315. First, prescriptions written in one state would, under some circumstances, be filled in a different state. But even more significantly, individuals transported opioids from one jurisdiction specifically to sell them in another.

316. When authorities in states cracked down on opioid suppliers, out-of-state suppliers filled the gaps. Florida in particular assumed a prominent role, as its lack of regulatory oversight created a fertile ground for pill mills. Residents of other states would simply drive to Florida, stock up on pills from a pill mill, and transport them back home to sell. The practice became so common that authorities dubbed these individuals "prescription tourists."

317. In another example, a man from Warren county, Ohio, sentenced to four years for transporting prescription opioids from Florida to Ohio, explained that he could get a prescription for 180 pills from a quick appointment in West Palm Beach, and that back home, people were willing to pay as much as $100 a pill—ten times the pharmacy price.[93] In Columbus, Ohio, a DEA investigation led to the 2011 prosecution of sixteen

[93] Andrew Welsh-Huggins, Associated Press, *'Prescription Tourists' Thwart States' Crackdown on Illegal Sale of Painkillers*, NBC News, available at http://www.nbcnews.com/id/

individuals involved in the "oxycodone pipeline between Ohio and Florida."[94] When officers searched the Ohio home of the alleged leader of the group, they found thousands of prescriptions pills, including oxycodone and hydrocodone, and $80,000 in cash. In 2015, another Columbus man was sentenced for the same conduct—paying couriers to travel to Florida and bring back thousands of prescription opioids, and, in the words of U.S. District Judge Michael Watson, contributing to a "pipeline of death."[95]

318. Outside of Atlanta, Georgia, four individuals pled guilty in 2015 to operating a pill mill; the U.S. attorney's office found that most of the pain clinic's customers came from other states.[96] Another investigation in Atlanta led to the 2017 conviction of two pharmacists who dispensed opioids to customers of a pill mill across from the pharmacy; many of those customers were from other states.[97]

319. In yet another case, defendants who operated a pill mill in south Florida within Broward County were tried in eastern Kentucky based on evidence that large numbers of customers transported oxycodone back to the area for both use and distribution by local drug trafficking organizations. As explained by the Sixth Circuit in

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48111639/ns/us_news-crime_and_courts/t/prescription-tourists-thwart-states-crackdown-illegal-sale-painkillers/#.WtdyKE2Wy71 (last updated July 8, 2012, 12:28 PM).

[94] *16 Charged in 'Pill Mill' Pipeline*, Columbus Dispatch (June 7, 2011), available at http://www.dispatch.com/content/stories/local/2011/06/07/16-charged-in-pill-mill-pipeline.html (last accessed July 25, 2018).

[95] Associated Press, Leader of Ohio Pill-Mill Trafficking Scheme Sentenced, Star Beacon (July 16, 2015), available at http://www.starbeacon.com/news/leader-of-ohio-pill-mill-trafficking-scheme-sentenced/article_5fb058f5-deb8-5963-b936-d71c279ef17c.html (last accessed July 25, 2018).

[96] Press Release, U.S. Dep't of Just., U.S. Atty's Off., Northern District of Ga., *Four Defendants Plead Guilty to Operating a "Pill Mill" in Lilburn, Georgia* (May 14, 2015), available at https://www.justice.gov/usao-ndga/pr/four-defendants-plead-guilty-operating-pill-mill-lilburn-georgia (last accessed July 25, 2018).

[97] Press Release, U.S. Dep't of Just., U.S. Atty's Off., Northern District of Ga., Two Pharmacists Convicted for Illegally Dispensing to Patients of a Pill Mill (Mar. 29, 2017), available at https://gdna.georgia.gov/press-releases/2017-03-30/two-pharmacists-convicted-illegally-dispensing-patients-pill-mill (last accessed July 25, 2018).

its decision upholding the venue decision, "[d]uring its existence, the clinic generated over $10 million in profits. To earn this sum required more business than the local market alone could provide. Indeed, only about half of the [Pain Center of Broward]'s customers came from Florida. Instead, the clinic grew prosperous on a flow of out-of-state traffic, with prospective patients traveling to the clinic from locations far outside Ft. Lauderdale, including from Ohio, Georgia, and Massachusetts."[98] The court further noted that the pill mill "gained massive financial benefits by taking advantage of the demand for oxycodone by Kentucky residents."[99]

320. The route from Florida and Georgia to Kentucky, Ohio, and West Virginia was so well traveled that it became known as the Blue Highway, a reference to the color of the 30mg Roxicodone pills manufactured by Mallinckrodt.[100] Eventually, as police began to stop vehicles with certain out-of-state tags cruising north on I-75, the prescription tourists adapted. They rented cars just over the Georgia state line to avoid the telltale out-of-state tag.[101] If they were visiting multiple pill mills on one trip, they would stop at FedEx between clinics to mail the pills home and avoid the risk of being caught with multiple prescriptions if pulled over.[102] Or they avoided the roads altogether: Allegiant Air, which offered several flights between Appalachia and Florida, was so popular with drug couriers that it was nicknamed the "Oxy Express."[103]

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[98] *United States v. Elliott*, 876 F.3d 855, 858 (6th Cir. 2017).
[99] *Id.* at 861.
[100] John Temple, *American Pain, How a Young Felon and His Ring of Doctors Unleashed America's Deadliest Drug Epidemic* 171 (2016).
[101] *Id.* at 172
[102] *Id*. at 171
[103] *Id.*

321. While the I-75 corridor was well utilized, prescription tourists also came from other states. The director of the Georgia drugs and narcotics agency observed that visitors to Georgia pill mills come from as far away as Arizona and Nebraska.[104]

322. Similar pipelines developed in other regions of the country. For example, the I-95 corridor was another transport route for prescription pills. As the director of the Maine Drug Enforcement Agency explained, the oxycodone in Maine was coming up extensively from Florida, Georgia and California.[105] And, according to the FBI, Michigan plays an important role in the opioid epidemic in other states; opioids prescribed in Michigan are often trafficked down to West Virginia, Ohio, and Kentucky.

323. Along the west coast, over a million pills were transported from the Lake Medical pain clinic in Los Angeles and cooperating pharmacies to the City of Everett, Washington.[106] Couriers drove up I-5 through California and Oregon, or flew from Los Angeles to Seattle.[107] The Everett-based dealer who received the pills from southern California wore a diamond necklace in the shape of the West Coast states with a trail of green gemstones—the color of 80-milligram OxyContin—connecting Los Angeles and Washington state.

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[104] Andrew Welsh-Huggins, Associated Press, *'Prescription Tourists' Thwart States' Crackdown on Illegal Sale of Painkillers*, NBC News, available at http://www.nbcnews.com/id/48111639/ns/usnews-crimeandcourts/t/prescription-tourists-thwart-states-crackdown-illegal-sale-painkillers/#.WtdyKE2Wy71 (last accessed July 25, 2018).

[105] Nok-Noi Ricker, *Slaying of Florida firefighter in Maine Puts Focus on Interstate 95 Drug Running*, Bangor Daily News (March 9, 2012), available at http://bangordailynews.com/2012/03/09/news/state/slaying-of-florida-firefighter-in-maine-puts-focus-on-interstate-95-drug-running (last accessed July 25, 2018)

[106] Harriet Ryan et al., How Black-Market OxyContin Spurred a Town's Descent into Crime, Addiction and Heartbreak, Los Angeles Times (July 10, 2016), available at http://www.latimes.com/projects/la-me-oxycontin-everett/ (last accessed July 25, 2018)

[107] *Id.*

324. Defendants certainly were aware, or should have been aware, that pill mills from around the country were pushing its products. Defendants purchased nationwide, regional, state, and local prescriber- and patient-level data from data vendors that allowed them to track prescribing trends, identify suspicious orders, identify patients who were doctor shopping, identify pill mills, etc. The data vendors' information purchased by the Defendants allowed them to view, analyze, compute, and track their competitors' sales, and to compare and analyze market share information.

325. Similarly, Wolters Kluwer, an entity that eventually owned data mining companies that were created by McKesson (Source) and Cardinal Health (ArcLight), provided the Defendants with charts analyzing the weekly prescribing patterns of multiple physicians, organized by territory, regarding competing drugs, and analyzed the market share of those drugs.

326. Not only were Defendants aware of the pill mills, but Defendants' sales incentives rewarded sales representatives who happened to have pill mills within their territories, enticing those representatives to look the other way even when their in-person visits to such clinics should have raised numerous red flags. In one example, a pain clinic in South Carolina was diverting massive quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away to get prescriptions, the DEA's diversion unit raided the clinic, and prosecutors eventually filed criminal charges against the doctors. But Purdue's sales representative for that territory, Eric Wilson, continued to promote OxyContin sales at the clinic. He reportedly told another local physician that this clinic accounted for 40% of the OxyContin sales in his territory. At that time, Wilson was Purdue's top-ranked sales representative. In response to news stories about this clinic,

Purdue issued a statement, declaring that "if a doctor is intent on prescribing our medication inappropriately, such activity would continue regardless of whether we contacted the doctor or not. [108]

327. In another example, a Purdue sales manager informed her supervisors in 2009 about a suspected pill mill in Los Angeles, reporting over email that when she visited the clinic with her sales representative "it was packed with a line out the door, with people who looked like gang members," and that she felt "very certain that this an organized drug ring[.]"[109] She wrote, "This is clearly diversion. Shouldn't the DEA be contacted about this?" But her supervisor at Purdue responded that while they were "considering all angles," it was "really up to [the wholesaler] to make the report."[110] This pill mill was the source of 1.1 million pills trafficked to Everett, Washington, a city of around 100,000 people. Purdue waited until after the clinic was shut down in 2010 to inform the authorities.

328. Abundant evidence, thus, establishes that prescription opioids migrated between states, counties, cities and tribes and that Defendants were aware of it. As a result, Defendants' public nuisance is not limited to the local or state level, but is national in scope. Additionally, prescription data from any particular jurisdiction does not capture the full scope of the misuse, oversupply and diversion problem in that specific area. As the criminal prosecutions referenced above show, if prescription opioid pills were hard to

[108] Barry Meier, *Pain Killer: A "Wonder" Drug's Trail of Addiction and Death* 204, 289-399 (Rodale 2003).

[109] Harriet Ryan *et al.*, *More Than 1 Million OxyContin Pills Ended Up in the Hands of Criminals and Addicts. What the Drugmaker Knew*, Los Angeles Time (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2/. (last accessed July 30, 2018)

[110] *Id.*

get in one area, they migrated from another. The manufacturers and distributors were fully aware of this phenomenon and profited from it.

I. Defendants' Unlawful Conduct and Breaches of Legal Duties Caused the Harm Alleged Herein and Substantial Damages

329. As the Manufacturer Defendants' efforts to expand the market for opioids increased, so have the rates of prescription and the sale of their products—and the rates of opioid-related substance abuse, hospitalization, and death among the Tribe's members and across the nation. Meanwhile, the Distributor Defendants have continued to unlawfully ship massive quantities of opioids into tribal communities, fueling the epidemic.

330. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes." [111]

331. Opioids are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions.[112]

332. The epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[113]

333. The increased abuse of prescription opioids—along with growing sales—has contributed to a large number of overdoses and deaths.

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[111] *See* Richard C. Dart et al., *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241 (2015).

[112] Volkow & McLellan, *supra* note 1.

[113] Califf, *supra* note 2.

334. As shown above, the opioid epidemic has escalated in the Tribe's community with devastating effects. Substantial opiate-related substance abuse, hospitalization, and death mirror Defendants' increased distribution of opioids.

335. Because of the well-established relationship between the use of prescription opioids and the use of non-prescription opioids, such as heroin, the massive distribution of opioids to the Tribe's community and areas from which opioids are being diverted to the Tribe, has caused the opioid epidemic to include heroin addiction, abuse, and death.

336. Prescription opioid abuse, addiction, morbidity, and mortality are hazards to public health and safety in the Tribe's community.

337. Heroin abuse, addiction, morbidity, and mortality are hazards to public health and safety in the Tribe's community.

338. Defendants repeatedly and purposefully breached their duties under state and federal law, and such breaches are direct and proximate causes of, and/or substantial factors leading to, the widespread diversion of prescription opioids for nonmedical purposes in the Tribe's community.

339. The unlawful diversion of prescription opioids is a direct and proximate cause of, and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, addiction, morbidity, and morality in the Tribe's community. This diversion and the resulting epidemic are direct causes of foreseeable harms incurred by the Tribe and members of the Tribe's community.

340. Defendants' intentional and unlawful conduct resulted in direct and foreseeable, past and continuing, economic damages for which the Tribe seeks relief, as

alleged herein. The Tribe also seeks the means to abate the epidemic created by the Defendants.

341. The Tribe seeks economic damages from the Defendants as reimbursement for the costs associated with past efforts to eliminate the hazards to public health and safety.

342. The Tribe seeks economic damages from the Defendants to pay for the costs to permanently eliminate the hazards to public health and safety and abate the public nuisance.

343. To eliminate the hazard to public health and safety, and abate the public nuisance, a "multifaceted, collaborative public health and law enforcement approach is urgently needed."[114]

344. A comprehensive response to this crisis must focus on preventing new cases of opioid addiction, identifying early opioid-addicted individuals, and ensuring access to effective opioid addiction treatment while safely meeting the need of patients experiencing pain.[115]

345. The community-based problems require community-based solutions that have been limited by budgetary constraints.

346. Having profited enormously through the aggressive sale, misleading promotion, and irresponsible distribution of opioids, Defendants should be required to

[114] Rudd, *supra* note 58.

[115] *See* Johns Hopkins Bloomberg School of Public Health, *The Prescription Opioid Epidemic: An Evidence-Based Approach* (G. Caleb Alexander et al., eds., 2015), available at https://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/research/prescription-opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf (last accessed January 8, 2018).

take responsibility for the financial burdens their conduct has inflicted upon the Tribe and the Tribe's community.

347. The opioid epidemic still rages because the fines and suspensions imposed by the DEA do not change the conduct of the industry. The Defendants pay fines as a cost of doing business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility.

348. The Defendants have abandoned their duties imposed by the law, have taken advantage of a lack of DEA enforcement, and have abused the privilege of distributing controlled substances in the Tribe's community.

349. In the course of conduct described in this Complaint, Defendants have acted with oppression, fraud, and malice, actual and presumed.

J. The Impact of Opioid Abuse on the Tribal Community

350. Defendants' creation, through false and misleading advertising and a failure to prevent diversion, of a virtually limitless opioid market has significantly harmed tribal communities and resulted in an abundance of drugs available for non-medical and criminal use, which in turn fueled a new wave of addiction and injury. It is estimated that approximately 60% of the opioids that are abused come, directly or indirectly, through doctors' prescriptions.

351. American Indians suffer the highest per capita rate of opioid overdoses.[116] And these overdose deaths among American Indians have increased fivefold between

[116] National Congress of American Indians, *Reflecting on a Crisis Curbing Opioid Abuse in Communities* (Oct. 2016), available at http://www.ncai.org/policy-research-center/research-data/prc-publications/Opioid_Brief.pdf (last accessed December 20, 2017).

1999 and 2015.[117] During that time period, American Indians accounted for roughly 22 overdose deaths in every 100,000 people in metropolitan areas and nearly 20 for every 100,000 people in non-metropolitan areas—a rate higher than any other group.[118]

352. The impact on American Indian children is particularly devastating. The CDC reported that approximately 1 in 10 American Indian youths ages 12 or older used prescription opioids for nonmedical purposes in 2012, which is double the rate for white youth.[119]

353. Opioid deaths represent the tip of the iceberg. Hospital admissions and emergency room visits have also skyrocketed.[120] For every opioid overdose death, there are 10 treatment admissions for abuse, 32 emergency room visits, 130 people who are addicted to opioids, and 825 nonmedical users of opioids.[121]

354. The fact that American Indian teens are able to easily obtain prescription opioids through the black market created by opioid diversion highlights the direct impact on the Tribe of Defendants' actions and inactions.

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[117] *Native American overdose deaths surge since opioid epidemic*, Associated Press, Mar. 15, 2018, available at https://apnews.com/81eb3ae96c2b4f6aae272ec50f 0672d2 (last accessed March 27, 2018).

[118] *Id.*

[119] *Id.*

[120] Lisa Girion and Karen Kaplan, *Opioids prescribed by doctors led to 92,000 overdoses in ERs in one year*, LA Times (Oct. 27, 2014), available at http://beta.latimes.com/nation/la-sci-sn-opioid-overdose-prescription-hospital-er-20141026-story.html (last accessed December 21, 2017).

[121] Jennifer DuPuis, Associate Dir., Human Servs. Div., Fond du Lac Band of Lake Superior Chippewa, *The Opioid Crisis in Indian Country*, at 37, available at https://www.nihb.org/docs/06162016/Opioid%20Crisis%20Part%20in%20Indian%20Country.pdf (last accessed December 21, 2017); Gery P. Guy, Jr., et al., *Emergency Department Visits Involving Opioid Overdoses, US., 2010-2014*, Am. J. of Preventive Medicine (Jan. 2018), available at http://www.ajpmonline.org/article/S0749-3797(17)30494-4/fulltext (last accessed December 21, 2017).

355. Even the Tribe's youngest members bear the consequences of the opioid abuse epidemic fueled by Defendants' conduct. In 1992, only 2 percent of women admitted for drug treatment services during pregnancy abused opioids. By 2012, opioids were the most commonly abused substance by pregnant women, accounting for 38 percent of all drug treatment admissions.[122] Many tribal women have become addicted to prescription opioids and have used these drugs during their pregnancies. As a result, many tribal infants suffer from opioid withdrawal and Neonatal Abstinence Syndrome ("NAS").[123]

356. Infants suffering from NAS are separated from their families and placed into the custody of the tribal child welfare services or receive other governmental services so they can be afforded medical treatment and be protected from drug-addicted parents.

357. The impact of NAS can be life-long. Most NAS infants are immediately transferred to a neonatal intensive care unit for a period of days, weeks, or even months. NAS can also require an emergency evacuation for care to save the infant's life. Such emergency transportation costs the Tribe thousands of dollars for each occurrence.

358. Many NAS infants have short-term and long-term developmental issues that prevent them from meeting basic cognitive and motor-skills milestones. Many will suffer from vision and digestive issues; some are unable to attend full days of school. These disabilities follow these children through elementary school and beyond.

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[122] Naana Afua Jumah, *Rural, Pregnant and Opioid Dependent: A Systematic Review*, National Institutes of Health, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4915786/ (last accessed December 21, 2017).

[123] Jean Y, Ko et al., *CDC Grand Rounds, Public Health Strategies to Prevent Neonatal Abstinence Syndrome*, U.S. C.D.C. Morbidity and Mortality Weekly Report, available at https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6609a2.pdf (last accessed December 21, 2017).

359. Pregnant American Indian women are up to 8.7 times[124] more likely to be diagnosed with opioid dependency or abuse compared to the next highest demographic, and in some communities upwards of 1 in 10 pregnant American Indian women has a diagnosis of opioid dependency or abuse.[125]

360. Many parents of these children continue to relapse into prescription opioid use and abuse. As a result, many of these children are placed in foster care or adopted.

361. Opioid diversion also contributes to a range of social problems, including physical and mental consequences, crime, delinquency, and mortality. Opioid abuse has also resulted in an explosion in heroin use. Almost 80% of those who used heroin in the past year previously abused prescription opioids. Other adverse social outcomes include child abuse and neglect, family dysfunction, criminal behavior, poverty, property damage, unemployment, and despair. More and more tribal resources are needed to combat these problems, leaving a diminished pool of already-scarce resources to devote to positive societal causes like education, cultural preservation, and other social programs. The Tribe faces a growing employment staffing problem, as critical services such as social services and victims' assistance programs have experienced high rates of employee turnover due to the opioid-related nature of the work. The prescription opioid crisis also diminishes the Tribe's available workforce, decreases productivity, increases poverty, and requires greater governmental expenditures by the Tribe. It also undermines the ability of the Tribe to self-govern and to maintain and develop economic independence.

[124] DuPuis, *supra* note 121, at 64.
[125] *Id.*

362. Idaho's reservations are geographically isolated, and the Indian Health Service, which provides health care on most reservations, including the Tribe's Reservation, has been underfunded for decades. Accordingly, Native Americans, like those living within the Reservation, often must travel farther than other Idahoans to access treatment centers and quality medical care.

363. The prescription opioid crisis has directly financially injured the Tribe. The crisis has led to an increased demand for, *inter alia*, police, child protective services, health services, clean-up services, and legal services on the reservation. The Tribe has also had to hire additional staff and expend additional resources to manage the demand.

364. The Tribe's health clinic has seen an increase in opioid-related health problems among tribal members, including, but not limited to, infants born with opioid-related medical conditions. This has resulted in increased demand, difficulty retaining staff, and increased expenses.

365. The Tribe has also suffered substantial financial damages in the form of lost productivity of tribal members, lost economic activity, lost reputation and good will, and the lost opportunity for growth and self-determination. These damages have been suffered and continue to be suffered directly by the Tribe.

366. Many patients who become addicted to opioids will lose their jobs. Some will lose their homes and their families. Some will get treatment and fewer will successfully complete it; many of those patients will relapse, returning to opioids or some other drug. Of those who continue to take opioids, some will overdose – some fatally, some not. Others will die prematurely from related causes – falling or getting into traffic accidents due to opioid-induced somnolence; dying in their sleep from opioid-induced respiratory depression; suffering assaults while engaging in illicit drug transactions; or

dying from opioid-induced heart or neurological disease. The opioid epidemic undermines the ability of the Tribe to self-govern and to maintain and develop economic independence.

367. While the use of opioids has taken an enormous toll on the Tribe and their people, Defendants have realized blockbuster profits. In 2014 alone, opioids generated $11 billion in revenue for drug companies like the Manufacturer Defendants. Indeed, on information and belief, each Defendant experienced a material increase in sales, revenue, and profits from the unlawful and unfair conduct described above.

K. The Statutes of Limitations Are Tolled and Defendants Are Estopped from Asserting Statutes of Limitations As Defenses

368. Defendants' conduct has continued from the early 1990s through today, and is still ongoing. The continued tortious and unlawful conduct by the Defendants causes a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has not ceased. The public nuisance remains unabated.

369. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook efforts to purposefully conceal their unlawful conduct and fraudulently assure the public that they were undertaking efforts to comply with their obligations under the controlled substances laws, all with the goal of continuing to generate profits.

370. For example, a Cardinal Health executive claimed that it uses "advanced analytics" to monitor its supply chain, and assured the public it was being "as effective

and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[126]

371. Similarly, McKesson publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."[127]

372. Defendants, through their trade associations, filed an amicus brief that represented that Defendants took their duties seriously, complied with their statutory and regulatory responsibilities, and monitored suspicious orders using advanced technology.[128]

373. Defendants purposely concealed their wrongful conduct, including by assuring the public and governmental authorities that they were complying with their obligations and were acting to prevent diversion and drug abuse. Defendants also misrepresented the impact of their behavior by providing the public with false information about opioids and have continued to use Front Groups and third parties to minimize the risks of Defendants' conduct. Defendants' conduct is continuing to this day.

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[126] Lenny Bernstein et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: "No One Was Doing Their Job,"* Wash. Post (Oct. 22, 2016), available at https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html (last accessed December 21, 2017)

[127] Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post, (Dec. 22, 2016), available at https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html (last accessed December 21, 2017).

[128] Br. for Healthcare Distribution Mgmt. Ass'n and Nat'l Ass'n of Chain Drug Stores as Amici Curiae in Support of Neither Party, Case No. 15-1335, 2016 WL 1321983, at *3-4, *25 (2d Cir. Apr. 4, 2016).

374. Defendants have also concealed and prevented discovery of information, including data from the ARCOS database, which will confirm their identities and the extent of their wrongful and illegal activities.

375. Defendants also lobbied Congress and actively attempted to halt DEA investigations and enforcement actions and to subvert the ability of agencies to regulate their conduct.[129] This led to a sharp drop in enforcement actions and the imposition of a more burdensome standard for the DEA to revoke a distributor's license.

376. In addition, the Defendants fraudulently attempted to convince the public that they were complying with their legal obligations and working to curb the opioid epidemic.

377. Because the Defendants concealed the facts surrounding the opioid epidemic, the Tribe did not know of the existence or scope of the Defendants' misconduct, and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

378. Defendants intended that their false statements and omissions be relied upon, including by the Tribe, its community, and its members.

379. Defendants knew of their wrongful acts and had material information pertinent to their discovery, but concealed that information from the public, including the Tribe, its community, and its members. Only Defendants knew of their widespread misinformation campaign and of their repeated, intentional failures to prevent opioid diversion.

[129] *See* Higham and Bernstein, *supra* note 61.

380. Defendants cannot claim prejudice due to a late filing because this suit was filed upon discovering the facts essential to the claim. Indeed, the existence, extent, and damage of the opioid crisis have only recently come to light.

381. Defendants had actual knowledge that their conduct was deceptive, and they intended it to be deceptive.

382. The Tribe was unable to obtain vital information regarding these claims absent any fault or lack of diligence on the Tribe's part.

L. Facts Pertaining to Punitive Damages

383. As set forth above, Defendants acted deliberately to increase sales of, and profits from, opioid drugs. The Marketing Defendants knew there was no support for their claims that addiction was rare, that addiction risk could be effectively managed, that signs of addiction were merely "pseudoaddiction," that withdrawal is easily managed, that higher doses pose no significant additional risks, that long-term use of opioids improves function, or that time-release or abuse-deterrent formulations would prevent addiction or abuse. Nonetheless, they knowingly promoted these falsehoods in order to increase the market for their addictive drugs.

384. All of the Defendants, moreover, knew that large and suspicious quantities of opioids were being poured into communities throughout the United States, yet, despite this knowledge, took no steps to report suspicious orders, control the supply of opioids, or otherwise prevent diversion. Indeed, as described above, Defendants acted in concert together to maintain high levels of quotas for their products and to ensure that suspicious orders would not be reported to regulators.

385. Defendants conduct was so willful and deliberate that it continued in the face of numerous enforcement actions, fines, and other warnings from state and local

governments and regulatory agencies. Defendants paid their fines, made promises to do better, and continued on with their marketing and supply schemes. This ongoing course of conduct knowingly, deliberately, and repeatedly threatened and accomplished harm and risk of harm to public health and safety, and large-scale economic loss to communities and government liabilities across the country.

386. Defendants' actions demonstrated both malice and also aggravated and egregious fraud. Defendants engaged in the conduct alleged herein with a conscious disregard for the rights and safety of other persons, even though that conduct had a great probability of causing substantial harm. The Marketing Defendants' fraudulent wrongdoing was done with a particularly gross and conscious disregard.

1. The Marketing Defendants Persisted in Their Fraudulent Scheme Despite Repeated Admonitions, Warnings and Prosecutions From Governmental and Regulatory Agencies

387. So determined were the Marketing Defendants to sell more opioids that they simply ignored multiple admonitions, warnings, and prosecutions. These governmental and regulatory actions included:

a. FDA Warnings to Janssen

388. FDA warnings to Janssen failed to deter Janssen's misleading promotion of Duragesic. On February 15, 2000, the FDA sent Janssen a letter concerning the dissemination of "homemade" promotional pieces that promoted the Janssen drug Duragesic in violation of the Federal Food, Drug and Cosmetic Act. In a subsequent letter dated March 30, 2000, the FDA explained that the "homemade" promotional pieces were "false or misleading because they contain misrepresentations of safety information, broaden Duragesic's indication, contain unsubstantiated claims, and lack fair balance."

The March 30, 2000 letter detailed numerous ways which Janssen's marketing was misleading.

389. The letter did not stop Janssen. On September 2, 2004 the U.S. Department of Health and Human Services ("HHS") sent Janssen a warning letter concerning Duragesic due to "false or misleading claims about the abuse potential and other risks of the drug, and…unsubstantiated effectiveness claims for Duragesic," including, specifically, "suggesting that Duragesic has a lower potential for abuse compared to other opioid products." The September 2, 2004 letter detailed a series of unsubstantiated, false, or misleading claims.

390. One year later, Janssen was still at it. On July 15, 2005, the FDA issued a public health advisory warning doctors of deaths resulting from the use of Duragesic and its generic competitor. The advisory noted that the FDA had been "examining the circumstances of product use to determine if the reported adverse events may be related to inappropriate use of the patch" and noted the possibility "that patients and physicians might be unaware of the risks" of using the fentanyl transdermal patch, which is a potent opioid analgesic approved only for chronic pain in opioid-tolerant patients that could not be treated by other drugs.

b. Cephalon Fined for Off-Label Marketing of Actiq

391. Government action, including large monetary fines, failed to stop Cephalon from falsely marketing Actiq for off-label uses. On September 29, 2008, Cephalon finalized and entered into a corporate integrity agreement with the Office of the Inspector General of HHS and agreed to pay $425 million in civil and criminal penalties for its off-label marketing of Actiq and two other drugs (Gabitril and Provigil).

According to a DOJ press release, Cephalon had trained sales representatives to disregard restrictions of the FDA-approved label, employed sales representatives and healthcare professionals to speak to physicians about off-label uses of the drugs and funded CME to promote off label uses.

392. Notwithstanding letters, an FDA safety alert, DOJ and state investigations, and the massive settlement, Cephalon has continued its deceptive marketing strategy.

c. Cephalon Ignored FDA Warnings Regarding Fentora Marketing

393. On September 27, 2007, the FDA issued a public health advisory to address numerous reports that patients who did not have cancer or were not opioid tolerant had been prescribed Fentora, and death or life-threatening side effects had resulted. The FDA warned: "Fentora should not be used to treat any type of short-term pain." Indeed, FDA specifically denied Cephalon's application, in 2008, to broaden the indication of Fentora to include treatment of non-cancer breakthrough pain and use in patients who were not already opioid-tolerant.

394. Flagrantly disregarding the FDA's refusal to broaden the indication for Fentora, Cephalon nonetheless marketed Fentora beyond its approved indications. On March 26, 2009, the FDA warned Cephalon against its misleading advertising of Fentora ("Warning Letter"). The Warning Letter described a Fentora internet advertisement as misleading because it purported to broaden "the indication for Fentora by implying that any patient with cancer who required treatment for breakthrough pain is a candidate for Fentora…when this is not the case." It further criticized Cephalon's other direct Fentora advertisements because they did not disclose the risks associated with the drug.

395. Despite this warning, Cephalon continued to use the same sales tactics to push Fentora as it did with Actiq. For example, on January 13, 2012, Cephalon published an insert in Pharmacy Times titled "An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA (Fentanyl Buccal Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate)." Despite the repeated warnings of the dangers associated with the use of the drugs beyond their limited indication, as detailed above, the first sentence of the insert states: "It is well recognized that the judicious use of opioids can facilitate effective and safe management of chronic pain."

d. Purdue Was Not Deterred from Fraudulently Marketing OxyContin

396. In May 2007, Purdue and three of its executives pled guilty to federal charges of misbranding OxyContin in what the company acknowledged was an attempt to mislead doctors about the risk of addiction. Purdue was ordered to pay $600 million in fines and fees. In its plea, Purdue admitted that its promotion of OxyContin was misleading and inaccurate, misrepresented the risk of addiction and was unsupported by science. Additionally, Michael Friedman, the company's president, pled guilty to a misbranding charge and agreed to pay $19 million in fines; Howard R. Udell, Purdue's top lawyer, also pled guilty and agreed to pay $8 million in fines; and Paul D. Goldenheim, its former medical director, pled guilty as well and agreed to pay 7.5 million in fines.

397. Nevertheless, even after the settlement, Purdue continued to pay doctors on speakers' bureaus to promote the liberal prescribing of OxyContin for chronic pain and fund seemingly neutral organizations to disseminate the message that opioids were non-addictive as well as other misrepresentations. At least until early 2018, Purdue

continued to deceptively market the benefits of opioids for chronic pain while diminishing the associated dangers of addiction. After Purdue made its guilty plea in 2017, it assembled an army of lobbyists to fight any legislative actions that might encroach on its business. Between 2006 and 2015, Purdue and other opioid producers, along with their associated nonprofits, spent nearly $900 million dollars on lobbying and political contributions – eight times what the gun lobby spent during that period.

2. Repeated Admonishments and Fines Did Not Stop Defendants from Ignoring Their Obligations to Control the Supply Chain and Prevent Diversion

398. Defendants were repeatedly admonished and even fined by regulatory authorities but continued to disregard their obligations to control the supply chain of dangerous opioids and to institute controls to prevent diversion.

399. Government actions against Defendants with respect to their obligations to control the supply chain and prevent diversion include:

a. On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against AmerisourceBergen Orlando Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration.

b. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone.

c. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone.

d. On December 7, 2007, the DEA issued an Order to Show Cause and

Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

e. On January 30, 2008, the DEA issued an Order to Show Cause against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone.

f. On September 30, 2008, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn, Lakeland, Swedesboro and Stafford Facilities. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"). Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility").

g. On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health's Lakeland Facility for failure to maintain effective controls against diversion of oxycodone.

h. On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland Facility.

400. McKesson's deliberate disregard of its obligations was especially flagrant. On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum Agreement ("2008 McKesson MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R §1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program."

401. Despite its 2008 agreement with DEA, McKesson continued to fail to report suspicious orders between 2008 and 2012 and did not fully implement or follow the monitoring program it agreed to. It failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers and bypassed suspicious order reporting procedures set forth in the CSMP. It failed to take these actions despite its awareness of the great probability that its failure to do so would cause substantial harm.

402. On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a $150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora, CO; Aurora, IL; Delran, NJ; LaCrosse, WI; Lakeland, FL; Landover, MD; La Vista, NE; Livonia, MI; Methuen, MA; Santa Fe Springs, CA; Washington Courthouse, OH; and West Sacramento, CA. McKesson's 2017 agreement with DEA shows that McKesson continued to breach its admitted duties by "fail[ing] to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations."

403. As *The Washington Post* and *60 Minutes* recently reported, DEA staff recommended a much larger penalty than the $150 million ultimately agreed to for McKesson's continued and renewed breach of its duties, as much as a billion dollars, and delicensing of certain facilities. A DEA memo outlining the investigative findings in connection with the administrative case against 12 McKesson distribution centers included in the 2017 Settlement stated that McKesson "[s]upplied controlled substances in support of criminal diversion activites"; "[i]gnored blatant diversion"; had a

"[p]attern of raising thresholds arbitrarily"; "[f]ailed to review orders or suspicious activity"; and "[i]gnored [company's] own procedures designed to prevent diversion."

404. Following the 2017 settlement, McKesson shareholders made a books and records request of the company. According to a separate action pending on their behalf, the Company's records show that the Company's Audit Committee failed to monitor McKesson's information reporting system to assess the state of the Company's compliance with the CSA and McKesson's 2008 Settlements. More particularly, the shareholder action alleges that the records show that in October 2008, the Audit Committee had an initial discussion of the 2008 Settlements and results of internal auditing, which revealed glaring omissions; specifically:

a. some customers had "not yet been assigned thresholds in the system to flag large shipments of controlled substances for review";

b. "[d]ocumentation evidencing new customer due diligence was incomplete";

c. "documentation supporting the company's decision to change thresholds for existing customers was also incomplete"; and

d. Internal Audit "identified opportunities to enhance the Standard Operating Procedures."

405. Yet, instead of correcting these deficiencies, after that time, for a period of more than four years, the Audit Committee failed to address the CSMP or perform any more audits of McKesson's compliance with the CSA or the 2008 Settlements, the shareholder action's description of McKesson's internal documents reveals. During that period of time, McKesson's Audit Committee failed to inquire whether the Company was in compliance with obligations set forth in those agreements and with the

controlled substance regulations more generally. It was only in January 2013 that the Audit Committee received an Internal Audit report touching on these issues.

406. In short, McKesson, was "neither rehabilitated nor deterred by the 2008 [agreement]," as a DEA official working on the case noted. Quite the opposite, "their bad acts continued and escalated to a level of egregiousness not seen before." According to statements of "DEA investigators, agents and supervisors who worked on the McKesson case" reported in *The Washington Post*, "the company paid little or no attention to the unusually large and frequent orders placed by pharmacies, some of them knowingly supplying the drug rings." Instead, the DEA officials said, the company raised its own self-imposed limits, known as thresholds, on orders from pharmacies and continued to ship increasing amounts of drugs in the face of numerous red flags."

407. Since at least 2002, Purdue has maintained a database of health care providers suspected of inappropriately prescribing OxyContin or other opioids. Physicians could be added to this database based on observed indicators of illicit prescribing such as excessive numbers of patients, cash transactions, patient overdoses, and unusual prescribing of the highest-strength pills (80 mg OxyContin pills or "80s", as they were known on the street, were a prime target for diversion). Purdue claims that health care providers added to the database no longer were detailed, and that sales representatives received no compensation tied to these providers' prescriptions.

408. Yet, Purdue failed to cut off these providers' opioid supply at the pharmacy level - meaning Purdue continued to generate sales revenue from their prescriptions – and failed to report these providers to state medical boards or law enforcement. Purdue's former senior compliance officer acknowledged in an interview

with the *Los Angeles Times* that in five years of investigating suspicious pharmacies, the company never stopped the supply of its opioids to a pharmacy, even where Purdue employees personally witnessed the diversion of its drugs.

409. The same was true of prescribers. For example, as discussed above, despite Purdue's knowledge of illicit prescribing from one Los Angeles clinic, which its district manager called an "organized drug ring" in 2009, Purdue did not report its suspicions until long after law enforcement shut it down and not until the ring prescribed more than 1.1 million OxyContin tablets.

410. Indeed, the New York Attorney General found that Purdue placed 103 New York health care providers on its "No-Call" List between January 1, 2008, and March 7, 2015, and yet Purdue's sales representatives had detailed approximately two-thirds of these providers, some quite extensively, making more than a total of 1,800 sales calls to their offices over a six-year period.

411. The New York Attorney General similarly found that Endo knew, as early as 2011, that Opana ER was being abused in New York, but certain sales representatives who detailed New York health care providers testified that they did not know about any policy or duty to report problematic conduct. The New York Attorney General further determined that Endo detailed health care providers who were subsequently arrested or convicted for illegal prescribing of opioids a total of 326 times, and these prescribers collectively wrote 1,370 prescriptions for Opana ER (although the subsequent criminal charges at issue did not involve Opana ER).

412. As all of the governmental actions against the Marketing Defendants and against all the Defendants shows, Defendants knew that their actions were unlawful,

and yet deliberately refused to change their practices because compliance with the legal obligations would have decreased their sales and their profits.

V. FACTS PERTAINING TO CLAIMS UNDER RICO

413. Defendants did not simply scheme to market opioids through misrepresentations and turning a blind eye to diversion. Various groups of Defendants also formed informal associations with others ("Enterprises") and used these Enterprises to perpetrate their schemes, as described below.

A. The Opioid Marketing Enterprise

1. The Common Purpose and Scheme of the Opioid Marketing Enterprise

414. Knowing that their opioids were highly addictive, ineffective, and unsafe for the treatment of long-term, chronic pain, non-acute, and non-cancer pain, Manufacturer Defendants formed an association-in-fact enterprise with the Front Groups and KOLs described above (the "Opioid Marketing Enterprise"). The Manufacturer Defendants used this Enterprise to engage in a scheme to increase their profits and sales unlawfully, and grow their share of the prescription painkiller market, through repeated and systematic misrepresentations about the safety and efficacy of opioids for treating long-term, chronic pain.

415. In order to unlawfully increase the demand for their name-brand and generic opioid products, the RICO Marketing Defendants (Purdue, Cephalon, Janssen, Endo, Teva, Allergan, Insys, and Mallinckrodt) formed an association-in-fact enterprise (the "Opioid Marketing Enterprise") with the "Front Groups" and KOLs described above. Through their personal relationships, the members of the Opioid Marketing Enterprise had the opportunity to form and take actions in furtherance of the Opioid Marketing

Enterprise's common purpose. The RICO Marketing Defendants' substantial financial contribution to the Opioid Marketing Enterprise, and the advancement of opioids-friendly messaging, fueled the U.S. opioids epidemic.

416. The RICO Marketing Defendants, through the Opioid Marketing Enterprise, concealed the true risks and dangers of opioids from the medical community and the public, including Plaintiff, and made misleading statements and misrepresentations about opioids that downplayed the risk of addiction and exaggerated the benefits of opioid use. The misleading statements included: (a) that addiction is rare among patients taking opioids for pain; (b) that addiction risk can be effectively managed; (c) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition the RICO Marketing Defendants named "pseudoaddiction"; (d) that withdrawal is easily managed; (e) that increased dosing presents no significant risks; (f) that long-term use of opioids improves function; (g) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (h) that use of time-released dosing prevents addiction; and (i) that abuse-deterrent formulations provide a solution to opioid abuse.

417. The scheme devised, implemented and conducted by the RICO Marketing Defendants was a common course of conduct designed to ensure that the RICO Marketing Defendants unlawfully increased their sales and profits through concealment and misrepresentations about the addictive nature and effective use of the RICO Marketing Defendants' drugs. The RICO Marketing Defendants, the Front Groups, and the KOLs acted together for a common purpose and perpetuated the Opioid Marketing Enterprise's

scheme, including through the unbranded promotion and marketing network as described above.

418. There was regular communication between the RICO Marketing Defendants, Front Groups and KOLs, in which information was shared, misrepresentations coordinated, and payments exchanged. Typically, the coordination, communication and payment occurred, and continues to occur, through the repeated and continuing use of the wires and mail in which the RICO Marketing Defendants, Front Groups, and KOLs share information regarding overcoming objections and resistance to the use of opioids for chronic pain. The RICO Marketing Defendants, Front Groups and KOLs functioned as a continuing unit for the purpose of implementing the Opioid Marketing Enterprise's scheme and common purpose, and each agreed and took actions to hide the scheme and continue its existence.

419. At all relevant times, the Front Groups were aware of the RICO Marketing Defendants' conduct, were knowing and willing participants in and beneficiaries of that conduct. Each Front Group also knew, but did not disclose, that the other Front Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and Plaintiff. But for the Opioid Marketing Enterprise's unlawful fraud, the Front Groups would have had incentive to disclose the deceit by the RICO Marketing Defendants and the Opioid Marketing Enterprise to their members and constituents. By failing to disclose this information, Front Groups perpetuated the Opioid Marketing Enterprise's scheme and common purpose, and reaped substantial benefits.

420. At all relevant times, the KOLs were aware of the RICO Marketing Defendants' conduct, were knowing and willing participants in that conduct, and reaped

benefits from that conduct. The RICO Marketing Defendants selected KOLs solely because they favored the aggressive treatment of chronic pain with opioids. The RICO Marketing Defendants' support helped the KOLs become respected industry experts. And, as they rose to prominence, the KOLs falsely touted the benefits of using opioids to treat chronic pain, repaying the RICO Marketing Defendants by advancing their marketing goals. The KOLs also knew, but did not disclose, that the other KOLs and Front Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and Plaintiff. But for the Opioid Marketing Enterprise's unlawful conduct, the KOLs would have had incentive to disclose the deceit by the RICO Marketing Defendants and the Opioid Marketing Enterprise, and to protect their patients and the patients of other physicians. By failing to disclose this information, KOLs furthered the Opioid Marketing Enterprise's scheme and common purpose, and reaped substantial benefits.

421. As public scrutiny and media coverage focused on how opioids ravaged communities in Idaho and throughout the United States, the Front Groups and KOLS did not challenge the RICO Marketing Defendants' misrepresentations, seek to correct their previous misrepresentations, terminate their role in the Opioid Marketing Enterprise, nor disclose publicly that the risks of using opioids for chronic pain outweighed their benefits and were not supported by medically acceptable evidence.

422. The RICO Marketing Defendants, Front Groups and KOLs engaged in certain discrete categories of activities in furtherance of the common purpose of the Opioid Marketing Enterprise. As described herein, the Opioid Marketing Enterprise's conduct in furtherance of the common purpose of the Opioid Marketing Enterprise

involved: (a) misrepresentations regarding the risk of addiction and safe use of prescription opioids for long-term chronic pain (described in detail above); (b) lobbying to defeat measures to restrict over-prescription; (c) efforts to criticize or undermine CDC guidelines; and (d) efforts to limit prescriber accountability.

423. In addition to disseminating misrepresentations about the risks and benefits of opioids, the Opioid Marketing Enterprise also furthered its common purpose by criticizing or undermining CDC guidelines. Members of the Opioid Marketing Enterprise criticized or undermined the CDC Guidelines which represented "an important step – and perhaps the first major step from the federal government - toward limiting opioid prescriptions for chronic pain."

424. Several Front Groups, including the U.S. Pain Foundation and the AAPM, criticized the draft guidelines in 2015, arguing that the "CDC slides presented on Wednesday were not transparent relative to process and failed to disclose the names, affiliation, and conflicts of interest of the individuals who participated in the construction of these guidelines."

425. The AAPM criticized the prescribing guidelines in 2016, through its immediate past president, stating "that the CDC guideline makes disproportionately strong recommendations based upon a narrowly selected portion of the available clinical evidence."

426. The RICO Marketing Defendants alone could not have accomplished the purpose of the Opioid Marketing Enterprise without the assistance of the Front Groups and KOLs, who were perceived as "neutral" and more "scientific" than the RICO Marketing Defendants themselves. Without the work of the Front Groups and KOLs in

spreading misrepresentations about opioids, the Opioid Marketing Enterprise could not have achieved its common purpose.

427. The impact of the Opioid Marketing Enterprise's scheme is still in place - i.e., the opioids continue to be prescribed and used for chronic pain throughout the Tribe, and the epidemic continues to injure Plaintiff, and consume the resources of Plaintiff's health care and law enforcement systems.

428. As a result, it is clear that the RICO Marketing Defendants, the Front Groups, and the KOLs were each willing participant in the Opioid Marketing Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Enterprise's purpose.

2. The Conduct of the Opioid Marketing Enterprise Violated RICO

429. From approximately the late 1990s to the present, each of the RICO Marketing Defendants exerted control over the Opioid Marketing Enterprise and participated in the operation or management of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. Creating and providing a body of deceptive, misleading and unsupported medical and popular literature about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

b. Creating and providing a body of deceptive, misleading and unsupported electronic and print advertisements about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

c. Creating and providing a body of deceptive, misleading and unsupported sales and promotional training materials about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii)

appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

d. Creating and providing a body of deceptive, misleading and unsupported CMEs and speaker presentations about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

e. Selecting, cultivating, promoting and paying KOLs based solely on their willingness to communicate and distribute the RICO Marketing Defendants' messages about the use of opioids for chronic pain;

f. Providing substantial opportunities for KOLs to participate in research studies on topics the RICO Marketing Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

g. Paying KOLs to serve as consultants or on the RICO Marketing Defendants' advisory boards, on the advisory boards and in leadership positions on Front Groups, and to give talks or present CMEs, typically over meals or at conferences;

h. Selecting, cultivating, promoting, creating and paying Front Groups based solely on their willingness to communicate and distribute the RICO Marketing Defendants' messages about the use of opioids for chronic pain;

i. Providing substantial opportunities for Front Groups to participate in and/or publish research studies on topics the RICO Marketing Defendants suggested or chose (and paid for), with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

j. Paying significant amounts of money to the leaders and individuals associated with Front Groups;

k. Donating to Front Groups to support talks or CMEs, that were typically presented over meals or at conferences;

l. Disseminating many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications from Front Groups;

m. Sponsoring CME programs put on by Front Groups that focused exclusively on the use of opioids for chronic pain;

n. Developing and disseminating pro-opioid treatment guidelines with the help of the KOLs as authors and promoters, and the help of the Front Groups as publishers, and supporters;

o. Encouraging Front Groups to disseminate their pro-opioid messages to groups targeted by the RICO Marketing Defendants, such as veterans and the elderly, and then funding that distribution;

p. Concealing their relationship to and control of Front Groups and KOLs from Plaintiff and the public at large; and

q. Intending that Front Groups and KOLs would distribute through the U.S. mail and interstate wire facilities, promotional and other materials that claimed opioids could be safely used for chronic pain.

430. The Opioid Marketing Enterprise had a hierarchical decision-making structure that was headed by the RICO Marketing Defendants and corroborated by the KOLs and Front Groups. The RICO Marketing Defendants controlled representations made about their opioids and their drugs, doled out payments to KOLs, and ensured that representations made by KOLs, Front Groups, and the RICO Marketing Defendants' sales detailers were consistent with the RICO Marketing Defendants' messaging throughout the United States and Idaho. The Front Groups and KOLS in the Opioid Marketing Enterprise were dependent on the RICO Marketing Defendants for their financial structure and for career development and promotion opportunities.

431. The Front Groups also conducted and participated in the conduct of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. The Front Groups promised to, and did, make representations regarding opioids and the RICO Marketing Defendants' drugs that were consistent with the RICO Marketing Defendants' messages;

b. The Front Groups distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction, and

misrepresented the benefits of using opioids for chronic pain outweighed the risks;

c. The Front Groups echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the RICO Marketing Defendants;

d. The Front Groups issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;

e. The Front Groups strongly criticized the 2016 guidelines from the Center for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain; and

f. The Front Groups concealed their connections to the KOLs and the RICO Marketing Defendants.

432. The RICO Marketing Defendants' Front Groups, "with their large numbers and credibility with policymakers and the public—have 'extensive influence in specific disease areas.'" The larger Front Groups "likely have a substantial effect on policies relevant to their industry sponsors."[130] "By aligning medical culture with industry goals in this way, many of the groups described in this report may have played a significant role in creating the necessary conditions for the U.S. opioid epidemic."

433. The KOLs also participated in the conduct of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. The KOLs promised to, and did, make representations regarding opioids and the RICO Marketing Defendants' drugs that were consistent with the RICO Marketing Defendants' messages themselves;

b. The KOLs distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain outweighed the risks;

[130] U.S. S. Homeland Sec. & Governmental Aff. Comm., Ranking Members' Office, *Fueling an Epidemic* (Feb. 12, 2018), available at https://www.hsdl.org/?abstract&did=808171

c. The KOLs echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the RICO Marketing Defendants;

d. The KOLs issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;

e. The KOLs strongly criticized the 2016 guidelines from the Center for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain; and

f. The KOLs concealed their connections to the Front Groups and the RICO Marketing Defendants, and their sponsorship by the RICO Marketing Defendants.

434. The scheme devised and implemented by the RICO Marketing Defendants and members of the Opioid Marketing Enterprise, amounted to a common course of conduct intended to increase the RICO Marketing Defendants' sales from prescription opioids by encouraging the prescribing and use of opioids for long-term chronic pain. The scheme was a continuing course of conduct, and many aspects of it continue through to the present.

3. The RICO Marketing Defendants Controlled and Paid Front Groups and KOLs to Promote and Maximize Opioid Use

435. As discussed in detail above, the RICO Marketing Defendants funded and controlled the various Front Groups, including APF, AAPM/APS, FSMB, USPF, and AGS. The Front Groups, which appeared to be independent, but were not, transmitted the RICO Marketing Defendants' misrepresentations. The RICO Marketing Defendants and the Front Groups thus worked together to promote the goals of the Opioid Marketing Enterprise.

436. The RICO Marketing Defendants worked together with each other through the Front Groups that they jointly funded and through which they collaborated on the joint promotional materials described above.

437. Similarly, as discussed in detail above, the RICO Marketing Defendants paid KOLs, including Drs. Portenoy, Fine, and Webster, to spread their misrepresentations and promote their products. The RICO Marketing Defendants and the KOLs thus worked together to promote the goals of the Opioid Marketing Enterprise.

4. Pattern of Racketeering Activity

438. The RICO Marketing Defendants' scheme described herein was perpetrated, in part, through multiple acts of mail fraud and wire fraud, constituting a pattern of racketeering activity as described herein.

439. The pattern of racketeering activity used by the RICO Marketing Defendants and the Opioid Marketing Enterprise likely involved thousands of separate instances of the use of the U.S. Mail or interstate wire facilities in furtherance of the unlawful Opioid Marketing Enterprise, including essentially uniform misrepresentations, concealments and material omissions regarding the beneficial uses and non-addictive qualities for the long-term treatment of chronic, non-acute and non-cancer pain, with the goal of profiting from increased sales of the RICO Marketing Defendants' drugs induced by consumers, prescribers, regulators and Plaintiff's reliance on the RICO Marketing Defendants' misrepresentations.

440. Each of these fraudulent mailings and interstate wire transmissions constitutes racketeering activity and collectively, these violations constitute a pattern of racketeering activity, through which the RICO Marketing Defendants, the Front Groups and the KOLs defrauded and intended to defraud Idaho consumers, the Tribe, and other intended victims.

441. The RICO Marketing Defendants devised and knowingly carried out an illegal scheme and artifice to defraud by means of materially false or fraudulent pretenses,

representations, promises, or omissions of material facts regarding the safe, non-addictive and effective use of opioids for long-term chronic, non-acute and non-cancer pain. The RICO Marketing Defendants and members of the Opioid Marketing Enterprise knew that these representations violated the FDA approved use these drugs, and were not supported by actual evidence. The RICO Marketing Defendants intended that that their common purpose and scheme to defraud would, and did, use the U.S. Mail and interstate wire facilities, intentionally and knowingly with the specific intent to advance, and for the purpose of executing, their illegal scheme.

442. By intentionally concealing the material risks and affirmatively misrepresenting the benefits of using opioids for chronic pain to prescribers, regulators and the public, including Plaintiff, the RICO Marketing Defendants, the Front Groups and the KOLs engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

443. The RICO Marketing Defendants' use of the U.S. Mail and interstate wire facilities to perpetrate the opioids marketing scheme involved thousands of communications, publications, representations, statements, electronic transmissions, payments, including, *inter alia*:

a. Marketing materials about opioids, and their risks and benefits, which the RICO Marketing Defendants sent to health care providers, transmitted through the internet and television, published, and transmitted to Front Groups and KOLs located across the country and Plaintiff's community;

b. Written representations and telephone calls between the RICO Marketing Defendants and Front Groups regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;

c. Written representations and telephone calls between the RICO Marketing Defendants and KOLs regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;

d. E-mails, telephone and written communications between the RICO Marketing Defendants and the Front Groups agreeing to or implementing the opioids marketing scheme;

e. E-mails, telephone and written communications between the RICO Marketing Defendants and the KOLs agreeing to or implementing the opioids marketing scheme;

f. Communications between the RICO Marketing Defendants, Front Groups and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Marketing Enterprise;

g. Communications between the RICO Marketing Defendants, KOLs and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Marketing Enterprise;

h. Written and oral communications directed to State agencies, federal and state courts, and private insurers throughout Plaintiff's community that fraudulently misrepresented the risks and benefits of using opioids for chronic pain; and

i. Receipts of increased profits sent through the U.S. Mail and interstate wire facilities—the wrongful proceeds of the scheme.

444. In addition to the above-referenced predicate acts, it was intended by and foreseeable to the RICO Marketing Defendants that the Front Groups and the KOLs would distribute publications through the U.S. Mail and by interstate wire facilities, and, in those publications, claim that the benefits of using opioids for chronic pain outweighed the risks of doing so.

445. To achieve the common goal and purpose of the Opioid Marketing Enterprise, the RICO Marketing Defendants and members of the Opioid Marketing Enterprise hid from the consumers, prescribers, regulators and Plaintiff: (a) the fraudulent

nature of the RICO Marketing Defendants' marketing scheme; (b) the fraudulent nature of statements made by the RICO Marketing Defendants and by their KOLs, Front Groups and other third parties regarding the safety and efficacy of prescription opioids; and (c) the true nature of the relationship between the members of the Opioid Marketing Enterprise.

446. The RICO Marketing Defendants, and each member of the Opioid Marketing Enterprise agreed, with knowledge and intent, to the overall objective of the RICO Marketing Defendants' fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in marketing prescription opioids.

447. Indeed, for the RICO Marketing Defendants' fraudulent scheme to work, each of them had to agree to implement similar tactics regarding fraudulent marketing of prescription opioids. This conclusion is supported by the fact that the RICO Marketing Defendants each financed, supported, and worked through the same KOLs and Front Groups, and often collaborated on and mutually supported the same publications, CMEs, presentations, and prescription guidelines.

448. The RICO Marketing Defendants' predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiff's business and property, while simultaneously generating billion-dollar revenue and profits for the RICO Marketing Defendants. The predicate acts were committed or caused to be committed by the RICO Marketing Defendants through their participation in the Opioid Marketing Enterprise and in furtherance of its fraudulent scheme.

B. The Opioid Supply Chain Enterprise

449. Faced with the reality that they will now be held accountable for the consequences of the opioid epidemic they created, members of the industry resort to "a

categorical denial of any criminal behavior or intent."[131] Defendants' actions went far beyond what could be considered ordinary business conduct. For more than a decade, certain Defendants, the "RICO Supply Chain Defendants" (AmerisourceBergen, Cardinal, McKesson, Purdue, Actavis, Cephalon, Endo, and Mallinckrodt) worked together in an illicit enterprise, engaging in conduct that was not only illegal, but in certain respects anti-competitive, with the common purpose and achievement of vastly increasing their respective profits and revenues by exponentially expanding a market that the law intended to restrict.

450. Knowing that dangerous drugs have a limited place in our society, and that their dissemination and use must be vigilantly monitored and policed to prevent the harm that drug abuse and addiction causes to individuals, society and governments, Congress enacted the Controlled Substances Act ("CSA"). Specifically, through the CSA, which created a closed system of distribution for controlled substances, Congress established an enterprise for good. CSA imposes a reporting duty that cuts across company lines. Regulations adopted under the CSA require that companies who are entrusted with permission to operate within this system cannot simply operate as competitive in an "anything goes" profit-maximizing market. Instead, the statute tasks them to watch over each other with a careful eye for suspicious activity. Driven by greed, Defendants betrayed that trust and subverted the constraints of the CSA's closed system to conduct their own enterprise for evil.

[131] McKesson Responds to Recent 60 Minutes Story About January 2017 Settlement With the Federal Government, McKesson, available at http://www.mckesson.com/about-mckesson/fighting-opioid-abuse/60-minutes-response (last visited Apr. 21, 2018).

451. As "registrants" under the CSA, the RICO Supply Chain Defendants are duty bound to identify and report "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[132] Critically, these Defendants' responsibilities do not end with the products they manufacture or distribute—there is no such limitation in the law because their duties cut across company lines. Thus, when these Defendants obtain information about the sales and distribution of other companies' opioid products, as they did through data mining companies like IMS Health, they were legally obligated to report that activity to the DEA.

452. If morality and the law did not suffice, competition dictates that the RICO Supply Chain Defendants would turn in their rivals when they had reason to suspect suspicious activity. Indeed, if a manufacturer or distributor could gain market share by reporting a competitor's illegal behavior (causing it to lose a license to operate, or otherwise inhibit its activity), ordinary business conduct dictates that it would do so. Under the CSA this whistleblower or watchdog function is not only a protected choice, but a statutory mandate. Unfortunately, however, that is not what happened. Instead, knowing that investigations into potential diversion would only lead to shrinking markets, the Rico Supply Chain Defendants elected to operate in a conspiracy of silence, in violation of both the CSA and RICO.

453. The RICO Supply Chain Defendants' scheme required the participation of all. If any one member broke rank, its compliance activities would highlight deficiencies of the others, and the artificially high quotas they maintained through their scheme would crumble. But, if all the members of the enterprise conducted themselves in the same

[132] 21 C.F.R. § 1301.74(b).

manner, it would be difficult for the DEA to go after any one of them. Accordingly, through the connections they made as a result of their participation in the Healthcare Distribution Alliance ("HDA"), the RICO Supply Chain Defendants chose to flout the closed system designed to protect the citizens. Publicly, in 2008, they announced their formulation of "Industry Compliance Guidelines: Reporting Suspicious Orders and Prevention Diversion of Controlled Substances." But, privately, the RICO Supply Chain Defendants refused to act and through their lobbying efforts, they collectively sought to undermine the impact of the CSA. Indeed, despite the issuance of these Industry Compliance Guidelines, which recognize these Defendants' duties under the law, as illustrated by the subsequent industry-wide enforcement actions and consent orders issued after that time, none of them complied. John Gray, President and CEO of the HDA said to Congress in 2014, it is "difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications." Yet, the RICO Supply Chain Defendants apparently all found the same profit-maximizing balance – intentionally remaining silent to ensure the largest possible financial return.

454. As described above, at all relevant times, the RICO Supply Chain Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues and profits by fraudulently increasing the quotas set by the DEA that would allow them to collectively benefit from a greater pool of prescription opioids to manufacture and distribute. In support of this common purpose and fraudulent scheme, the RICO Supply Chain Defendants jointly agreed to disregard their statutory duties to identify, investigate, halt and report suspicious orders of opioids

and diversion of their drugs into the illicit market so that those orders would not result in a decrease, or prevent an increase in, the necessary quotas.

455. At all relevant times, as described above, the RICO Supply Chain Defendants exerted control over, conducted and/or participated in the Opioid Supply Chain Enterprise by fraudulently claiming that they were complying with their duties under the CSA to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, and to halt such unlawful sales, so as to increase production quotas and generate unlawful profits, as follows:

456. The RICO Supply Chain Defendants disseminated false and misleading statements to state and federal regulators claiming that:

a. the quotas for prescription opioids should be increased;

b. they were complying with their obligations to maintain effective controls against diversion of their prescription opioids;

c. they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids;

d. they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids; and

e. they did not have the capability to identify suspicious orders of controlled substances.

457. The Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations

pending investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."[133]

458. The CSA and the Code of Federal Regulations, require the RICO Supply Chain Defendants to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders. The failure to make reports as required by the CSA and Code of Federal Regulations amounts to a criminal violation of the statute.

459. The RICO Supply Chain Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other document required to be filed with the DEA including the Marketing Defendants' applications for production quotas. Specifically, the RICO Supply Chain Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

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[133] *HDMA is Now the Healthcare Distribution Alliance*, Pharmaceutical Commerce, available at http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/ (last updated July 6, 2016); Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post (Oct. 22, 2016), available at https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the- opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13- d7c704ef9fd9_story.html (last accessed December 21, 2017); Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post (Mar. 6, 2017), available at https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html (last accessed December 21, 2017); Eric Eyre, *DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail (Feb. 18, 2017), available at http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills- (last accessed December 21, 2017).

460. The RICO Supply Chain Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

461. In devising and executing the illegal scheme, the RICO Supply Chain Defendants devised and knowingly carried out a material scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts.

462. For the purpose of executing the illegal scheme, the RICO Supply Chain Defendants committed racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme. These racketeering acts, which included repeated acts of mail fraud and wire fraud, constituted a pattern of racketeering.

463. The RICO Supply Chain Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Marketing Defendants, the Distributor Defendants, or third parties that were foreseeably caused to be sent as a result of the RICO Supply Chain Defendants' illegal scheme, including but not limited to:

a. The prescription opioids themselves;

b. Documents and communications that supported and/or facilitated the RICO Supply Chain Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;

c. Documents and communications that facilitated the manufacture, purchase and sale of prescription opioids;

d. RICO Supply Chain Defendants' DEA registrations;

e. Documents and communications that supported and/or facilitated RICO Supply Chain Defendants' DEA registrations;

f. RICO Supply Chain Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;

g. Documents and communications related to the RICO Supply Chain Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;

h. Documents intended to facilitate the manufacture and distribution of the RICO Supply Chain Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence;

i. Documents for processing and receiving payment for prescription opioids;

j. Payments from the Distributors to the Marketing Defendants;

k. Rebates and chargebacks from the Marketing Defendants to the Distributors Defendants;

l. Payments to the RICO Supply Chain Defendants' lobbyists through the PCF;

m. Payments to the RICO Supply Chain Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;

n. Deposits of proceeds from the RICO Supply Chain Defendants' manufacture and distribution of prescription opioids; and

o. Other documents and things, including electronic communications.

464. The RICO Supply Chain Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce.

465. The RICO Supply Chain Defendants used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the RICO Supply Chain Defendants made misrepresentations about their compliance with federal and state laws requiring them to identify, investigate and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

466. At the same time, the RICO Supply Chain Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids, and their compliance with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

467. The RICO Supply Chain Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

468. The RICO Supply Chain Defendants also communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail with each other and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

469. The mail and wire transmissions described herein were made in furtherance of the RICO Supply Chain Defendants' scheme and common course of conduct to deceive regulators, the public and Plaintiff that these Defendants were complying with their state and federal obligations to identify and report suspicious orders of prescription opioids all while Defendants were knowingly allowing millions of doses

of prescription opioids to divert into the illicit drug market. The RICO Supply Chain Defendants' scheme and common course of conduct was to increase or maintain high production quotas for their prescription opioids from which they could profit.

470. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden by Defendants and cannot be alleged without access to Defendants' books and records. However, Plaintiff has described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

471. The RICO Supply Chain Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with these Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for the RICO Supply Chain Defendants.

472. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

473. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiff's business and property, while simultaneously generating billion-dollar revenue and profits for the RICO Supply Chain Defendants. The predicate acts were committed or caused to be committed by the Defendants through their participation in the Opioid Supply Chain Enterprise and in furtherance of its fraudulent scheme.

474. As described above, the RICO Supply Chain Defendants were repeatedly warned, fined, and found to be in violation of applicable law and regulations, and yet they persisted. The sheer volume of enforcement actions against the RICO Supply Chain Defendants supports this conclusion that the RICO Supply Chain Defendants operated through a pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74.

475. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, Plaintiff's community and Plaintiff. The RICO Supply Chain Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on this jurisdiction, its citizens or Plaintiff. The RICO Supply Chain Defendants were aware that Plaintiff and the citizens of these jurisdictions rely on these Defendants to maintain a closed system of manufacturing and distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

476. By intentionally refusing to report and halt suspicious orders of their prescription opioids, the RICO Supply Chain Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

VI. CAUSES OF ACTION

COUNT I: PUBLIC NUISANCE
Federal Common Law
Against All Defendants

477. Plaintiff realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

478. "The elements of a claim based on the federal common law of nuisance are simply that the defendant is carrying on an activity that is causing an injury or significant threat of injury to some cognizable interest of the complainant." *Illinois v. City of Milwaukee,* 599 F.2d 151, 165 (7th Cir. 1979), *rev'd on other grounds, Milwaukee II,* 451 U.S. 304.

479. The Second Restatement, which "has been a common reference point for courts considering cases arising under federal common law" *Michigan v. U.S. Army Corps of Engineers*, 758 F.3d 892, 900 (7th Cir. 2014), defines a public nuisance as "an unreasonable interference with a right common to the general public." Restatement (Second) of Torts § 821B(1) (1979) (defining public nuisance, in part, as a significant interference with the public health, safety, peace, comfort, or convenience).

480. The Supreme Court, when analyzing claims under the federal common law of public nuisance, has observed that "common law generally, adapts to changing scientific and factual circumstances." *Am. Elec. Power Co. v. Connecticut*, 564 U.S. 410, 423 (2011). Other Circuit courts have observed that the Supreme Court's jurisprudence "reflects [a] broad understanding" of the public nuisance doctrine and that "[p]ublic

nuisance traditionally has been understood to cover a tremendous range of subjects." *Michigan v. U.S. Army Corps of Engineers*, 667 F.3d 765, 771-772 (7th Cir. 2011).

481. As more fully alleged in the preceding Paragraphs of this Complaint, Defendants' deliberately deceptive, coordinated, and nationwide marketing strategy to expand name-brand and generic opioid use, together with their equally deliberate efforts to evade restrictions on opioid distribution, has caused substantial and unreasonable interference with Plaintiff and Plaintiff's community's public rights, including, but not limited to, the public's right to health, safety, welfare, peace, comfort, convenience, and ability to be free from disturbance and reasonable apprehension of danger to person or property.

482. Specifically, Manufacturer Defendants unreasonably interfered with Plaintiff and Plaintiff's community's public rights by, *inter alia*, engaging in an intentional, nationwide promotion and marketing scheme that pushed the use of opioids for indications not federally approved, and by circulating false and misleading information concerning their risks, benefits, and superiority, and/or downplaying or omitting the risk of addiction arising from their use. And when Manufacturer Defendants were aware that the marketing scheme was working, they did not take appropriate action to educate doctors, healthcare providers and the medical community on the proper use of and abuse and addiction risks associated with their name-brand and generic opioid products as set forth in their opioid product labels. In so doing, Manufacturer Defendants failed to comply with federal law.

483. Defendants have also unlawfully, intentionally, and unreasonably distributed opioids or caused opioids to be distributed without maintaining effective

controls against diversion. Defendants' distribution scheme worked as an illicit enterprise, and was driven by national policies, coordination, plans, and procedures that were the same in Idaho as they were across the country. Such conduct was illegal and proscribed by statute and regulation. Defendants' failures to maintain effective controls against diversion include Defendants' failure to effectively monitor for suspicious orders, report suspicious orders, and/or stop shipment of suspicious orders.

484. Defendants intentionally and unlawfully manufactured, marketed, distributed, and sold prescription opioids that Defendants know, or reasonably should know, would be diverted across various jurisdictions, causing widespread distribution of prescription opioids in Plaintiff's community, resulting in addiction and abuse, an elevated level of crime, death and injuries, a higher level of fear, discomfort and inconvenience, and direct costs to Plaintiff and Plaintiff's community.

485. Defendants' actions and its impacts were, and continue to be, inherently transboundary in nature. When individual states, counties, cities, or tribal communities implemented stricter measures on the sales of opioids, out-of-state suppliers filled the gaps. Prescriptions for opioids manufactured and distributed in one jurisdiction were regularly transported for sale in another. Additionally, prescriptions written in one jurisdiction would, under some circumstances, be filled in a different jurisdiction. The manufacturers and distributors were fully aware of this phenomenon and profited from it.

486. There is a uniquely federal interest associated with the widespread, and transboundary nature of the prescription opioid epidemic and the federal common law is an appropriate vehicle to address Plaintiff's claims.

487. Defendants' interference with Plaintiff and Plaintiff's community's public rights include, but are not limited to, the effects of addiction, abuse, elevated crime, deaths, and increased expenditures to combat and address these harms. These damages have been suffered and continue to be suffered directly by Plaintiff and Plaintiff's community.

488. Defendants' actions have also created a palpable climate of fear, distress, dysfunction and chaos among residents in Plaintiff's community where opioid diversion, abuse, and addiction are prevalent and where diverted opioids tend to be used frequently.

489. Specifically, Defendants' conduct has caused, *inter alia*,:

a. Children to fall victim to the opioid epidemic. Easy access to prescription opioids made opioids a recreational drug of choice among teenagers. Even infants have been born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts.

b. Children to be routinely separated from their parents, who have fallen victim to easy access to opioids and/or related crime.

c. Many residents to endure both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids.

d. Increased crime and/or destruction of public spaces and property.

e. Property crimes throughout Plaintiff's community as addicts search for the means to finance their addiction.

f. Employers to lose the value of productive and healthy employees.

g. Resources to be diverted from other important public uses in order to fund public services most heavily impacted by the opioid epidemic.

h. A decrease in property values within the Tribe

490. Defendants' impact on Plaintiff and Plaintiff's community is of a continuing nature. Defendants' conduct will undoubtedly continue to cause long-lasting effects on the public rights of Plaintiff and Plaintiff's community.

491. Defendants know or should have known that their actions would lead to the national opioid epidemic and to the resulting injuries to the public rights of Plaintiff and of Plaintiff's community.

492. The externalized risks associated with Defendants' nuisance-creating conduct as described herein greatly exceed the internalized benefits.

493. Plaintiff has sustained specific and special injuries because its damages include, *inter alia*, health service expenditures, law enforcement expenditures, payment of prescription opioids and opioid addiction treatment through its healthcare program, casino revenue losses, and other costs related to opioid addiction treatment and overdose prevention.

494. Defendants' actions are a direct and proximate contributing cause of the national opioid epidemic and of the injuries to the public rights of Plaintiff and Plaintiff's community.

495. Defendants' actions, individually and collectively, are at the very least, a substantial factor in causing the national opioid epidemic and the injuries to the public rights of Plaintiff and Plaintiff's community.

496. The injuries to the public rights of Plaintiff and Plaintiff's community are indivisible.

497. Defendants' manufacture, marketing, distribution, and sale of prescription opioids, if unabated, will continue to cause an unreasonable interference with public rights of Plaintiff and Plaintiff's community.

498. Defendants are jointly and severally liable under the federal common law of public nuisance.

499. Defendants' conduct is ongoing and persistent, and Plaintiff seeks all damages flowing from Defendants' conduct. Plaintiff seeks economic losses (direct, incidental, and/or consequential pecuniary losses) resulting from Defendants illegal and wrongful conduct described above. Plaintiff does not seek damages for the wrongful death, physical personal injury, or emotional distress caused by Defendants' actions.

500. Plaintiff further seeks to abate the nuisance and harm created by Defendants' conduct.

501. Plaintiff's injuries, as alleged throughout this Complaint, are expressly incorporated herein by reference. Plaintiff seeks all legal and equitable relief as allowed by law, including, *inter alia*, abatement, compensatory damages, and punitive damages from the Defendants for the creation of a public nuisance, attorney fees and costs, as well as pre- and post-judgment interest.

COUNT II: PUBLIC NUISANCE
Idaho Code § 52-101 Et Seq. And Common Law
Against All Defendants

502. In the alternative to the First Cause of Action, if federal common law were not to apply, Defendants are liable to Plaintiff under the applicable state common law and/or statutory law of public nuisance (Idaho Code. § 52-101 *et seq*.).

503. Plaintiff realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

504. Plaintiff alleges that Defendants actions have created a public nuisance. Each Defendant is liable for public nuisance because its conduct at issue is intentional, unreasonable, and unlawful, and has created an epidemic which annoys, injures or endangers the safety, health, morals, comfort, or repose of a considerable number of members of Plaintiff's community. Defendants' conduct is also indecent or offensive to the senses, and constitutes an obstruction to the free use of property sufficient to constitute an interference with Plaintiff and Plaintiff's community's comfortable enjoyment of life or property.

505. As more fully alleged in the preceding Paragraphs of this Complaint, Defendants' intentional and deliberately deceptive marketing strategy to expand opioid use, together with their equally deliberate efforts to evade restrictions on opioid distribution has caused substantial and unreasonable interference with Plaintiff and Plaintiff's community's public rights, including, but not limited to, the public's right to health, safety, welfare, peace, comfort, convenience, and ability to be free from disturbance and reasonable apprehension of danger to person or property.

506. Specifically, Manufacturer Defendants intentionally, unlawfully, and unreasonably interfered with Plaintiff and Plaintiff's community's public rights by, *inter alia*, engaging in a promotion and marketing scheme that pushed the use of opioids for indications not federally approved, and by circulating false and misleading information concerning their risks, benefits, and superiority, and/or downplaying or omitting the risk of addiction arising from their use. And when Manufacturer Defendants were aware that

the marketing scheme was working, they did not take appropriate action to educate doctors, healthcare providers and the medical community on the proper use of and abuse and addiction risks associated with their name-brand and generic opioid products as set forth in their opioid product labels. In so doing, Manufacturer Defendants failed to comply with federal law.

507. Defendants have also unlawfully and intentionally distributed opioids or caused opioids to be distributed within and without Plaintiff's community absent effective controls against diversion. Such conduct was illegal, and proscribed by statute and regulation. Defendants' failures to maintain effective controls against diversion include Defendants' failure to effectively monitor for suspicious orders, report suspicious orders, and/or stop shipment of suspicious orders.

508. Defendant's unreasonable interference with Plaintiff's community's public rights include, but are not limited to, the effects of addiction, abuse, elevated crime, deaths, and increased expenditures to combat and address these harms. Plaintiff has also paid costs of opioid prescriptions for chronic pain paid directly through the Tribe's healthcare program, dispensed as a direct result of Defendants' widespread, pervasive, misleading, and effective opioid marketing campaign. Plaintiff has also made payments through its healthcare program for opioid addiction treatment. These damages have been suffered and continue to be suffered directly by Plaintiff and Plaintiff's community.

509. Defendants' actions have also created a palpable climate of fear, distress, dysfunction and chaos among residents in Plaintiff's community where opioid diversion, abuse, and addiction are prevalent and where diverted opioids tend to be used frequently. Specifically, Defendants conduct has caused (a) routine separation of children from their

parents who have fallen victim to easy access to opioids and/or related crime; (b) children to have easy access and to become addicted to opioids; (c) residents to endure both the emotional and financial costs of caring for loved ones addicted to or injured by opioids; (d) increased crime and/or destruction of public spaces and property; (e) property crimes throughout Plaintiff's community; (f) employers to lose the value of productive and healthy employees; (g) resources to be diverted from other important public uses; and (h) a decrease in property values within the Tribe.

510. Defendants' conduct's impact on Plaintiff and Plaintiff's community is of a continuing nature. Defendants' conduct will undoubtedly continue to cause long-lasting effects on their public rights.

511. Defendants knew or should have known that their actions would lead to the national opioid epidemic and to the resulting injuries to the public rights of Plaintiff and of Plaintiff's community.

512. Plaintiff has sustained a special and peculiar injury because its damages include, *inter alia*, health service expenditures, law enforcement expenditures, lost casino revenue, payment of prescription opioids and opioid addiction treatment through its healthcare program, and other costs related to opioid addiction treatment and overdose prevention.

513. The externalized risks associated with Defendants' nuisance-creating conduct as described herein greatly exceed the internalized benefits.

514. Defendants' actions are a direct and proximate contributing cause of the opioid epidemic and the injuries to the public rights of Plaintiff and Plaintiff's community.

515. Defendants, individually and collectively, are at the very least, a substantial factor in causing the national opioid epidemic and of the injuries to the public rights of Plaintiff and Plaintiff's community.

516. The injuries to the public rights of Plaintiff and Plaintiff's community are indivisible injuries.

517. Defendants' manufacture, marketing, distribution, and sale of prescription opioids, if unabated, will continue to cause an unreasonable interference with public rights of Plaintiff and Plaintiff's community.

518. Defendants' conduct is ongoing and persistent, and Plaintiff seeks all damages flowing from Defendants' conduct. Plaintiff seeks economic losses (direct, incidental, and/or consequential pecuniary losses) resulting from Defendants' illegal and wrongful conduct described above. Plaintiff does not seek damages for the wrongful death, physical personal injury, or emotional distress caused by Defendants' actions.

519. Plaintiff's injuries, as alleged throughout this Complaint, are expressly incorporated herein by reference. Plaintiff seeks all legal and equitable relief as allowed by law, including, *inter alia*, abatement, compensatory damages, and punitive damages from the Defendants for the creation of a public nuisance, attorney fees and costs, as well as pre- and post-judgment interest.

COUNT III: RACKETEER-INFLUENCED AND CORRUPT ORGANIZATIONS ACT, 18 U.S.C. § 1961 Et Seq. - Opioid Marketing Enterprise
(Against Manufacturer Defendants – "Rico Marketing Defendants")

520. Plaintiff realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

521. At all relevant times, the RICO Marketing Defendants were and are "persons" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

522. The Opioid Marketing Enterprise was an association-in-fact enterprise that consisted of the RICO Marketing Defendants; the Front Groups; and the KOLs. The activities of this enterprise affected interstate commerce.

523. The RICO Marketing Defendants (a) through the use of "Front Groups" that appeared to be independent of the RICO Marketing Defendants; (b) through the dissemination of publications that supported the RICO Marketing Defendants scheme; (c) through continuing medical education ("CME") programs controlled and/or funded by the RICO Marketing Defendants; (d) by the hiring and deployment of so-called "key opinion leaders," ("KOLs") who were paid by the RICO Marketing Defendants to promote their message; and (e) through the "detailing" activities of the RICO Marketing Defendants' sales forces, conducted an association-in-fact enterprise, and/or participated in the conduct of that enterprise through a pattern of illegal activities (the predicate racketeering acts of mail and wire fraud) to carry out the common purpose of the Opioid Marketing Enterprise, i.e., to increase unlawfully profits and revenues from the continued prescription and use of name-brand and generic opioids for long-term chronic pain and through creating widespread dependency on and addiction to opioids. The Opioid Marketing Enterprise sought to further this common purpose through a fraudulent scheme to change prescriber habits and public perception about the safety and efficacy of opioid use. In so doing, each of the RICO Marketing Defendants knowingly conducted and

participated in the conduct of the Opioid Marketing Activities by engaging in mail and wire fraud in violation of 18 U.S.C. § 1962(c) and (d).

524. Each of the RICO Marketing Defendants and the other members of the Opioid Marketing Enterprise conducted and participated in the conduct of the Opioid Marketing Enterprise by playing a role in furthering the enterprise's common purpose of increasing profits and sales through the knowing and intentional dissemination of false and misleading information about the safety and efficacy of long-term opioid use.

525. The RICO Marketing Defendants worked together to coordinate the Enterprise's goals and conceal their role, and the Enterprise's existence, from the public by, among other things, (a) funding, editing, and distributing publications that supported and advanced their false messages; (b) funding KOLs to promote their false messages; (c) funding, editing, and distributing CME programs to advance their false messages; and (d) tasking their own employees to direct deceptive marketing materials and pitches directly at physicians and, in particular, at physicians lacking the expertise of pain care specialists (that is, sales detailing).

526. Each of the Front Groups helped disguise the role of RICO Marketing Defendants by purporting to be unbiased, independent patient-advocacy and professional organizations in order to disseminate patient education materials, a body of biased and unsupported scientific "literature," and "treatment guidelines" that promoted the RICO Marketing Defendants' false messages.

527. Each of the KOLs were physicians chosen and paid by each of the RICO Marketing Defendants to influence prescribers' habits by promoting the RICO Marketing Defendants' false message through, among other things, writing favorable journal articles

and delivering supportive CMEs as if they were independent medical professionals, thereby further obscuring the RICO Marketing Defendants' role in the Opioid Marketing Enterprise and the Opioid Marketing Enterprise's existence.

528. Further, each of the RICO Marketing Defendants, KOLs, and Front Groups that made-up the Opioid Marketing Enterprise had systematic links to and personal relationships with each other through (a) joint participation in lobbying groups, (b) trade industry organizations, (c) contractual relationships, and (d) continuing coordination of activities. These systematic links and personal relationships allowed members of the Opioid Marketing Enterprise to act with a common purpose and agree to conduct and participate in the conduct of the Opioid Marketing Enterprise. Specifically, each of the RICO Marketing Defendants coordinated their efforts through the same KOLs and Front Groups, based on their agreement and understanding that the Front Groups and KOLs were industry-friendly and would work together with the RICO Marketing Defendants to advance the common purpose of the Opioid Marketing Enterprise. And each of the individuals and entities who formed the Opioid Marketing Enterprise acted to enable the common purpose and fraudulent scheme of the Opioid Marketing Enterprise.

529. At all relevant times, the Opioid Marketing Enterprise: (a) had an existence separate and distinct from each member of the Opioid Marketing Enterprise; (b) was separate and distinct from the pattern of racketeering in which the RICO Marketing Defendants engaged; (c) was an ongoing and continuing organization consisting of individuals, persons, and legal entities, including each of the RICO Marketing Defendants; (d) was characterized by interpersonal relationships between and among each member of the Opioid Marketing Enterprise, including between the RICO

Marketing Defendants and each of the Front Groups and KOLs; and (e) had sufficient longevity for the enterprise to pursue its purpose and functioned as a continuing unit.

530. The RICO Marketing Defendants conducted and participated in the conduct of the Opioid Marketing Enterprise through a pattern of racketeering activity that employed the use of mail and interstate wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud), to increase profits and revenue by changing prescriber habits and public perceptions in order to increase the prescription and use of prescription opioids.

531. The RICO Marketing Defendants each committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e. violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years.

532. The multiple acts of racketeering activity that the RICO Marketing Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity and/or constituted continuous racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the RICO Marketing Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Marketing Enterprise. The RICO Marketing Defendants participated in the scheme to defraud by using mail, telephones, and the internet to transmit mailings and wires in interstate or foreign commerce.

533. The RICO Marketing Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

a. Mail Fraud: The RICO Marketing Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received,

materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, false promises, and omissions.

b. Wire Fraud: The RICO Marketing Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by interstate wires for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, false promises, and omissions.

534. Indeed, as summarized herein, the RICO Marketing Defendants used the mail and interstate wires to send or receive thousands of communications, publications, representations, statements, electronic transmissions, and payments to carry out the Opioid Marketing Enterprise's fraudulent scheme.

535. Because the RICO Marketing Defendants disguised their participation in the Opioid Marketing Enterprise, and worked to keep even the Opioid Marketing Enterprise's existence secret so as to give the false appearance that their false messages reflected the views of independent third parties, many of the precise dates of the Opioid Marketing Enterprise's uses of the U.S. Mail and interstate wire facilities (and corresponding predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to the books and records maintained by the RICO Marketing Defendants, Front Groups, and KOLs. Indeed, an essential part of the successful operation of the Opioid Marketing Enterprise depended upon secrecy. However, Plaintiff has described occasions on which the RICO Marketing Defendants, Front Groups, and KOLs disseminated misrepresentations and false statements to consumers, prescribers, regulators and Plaintiff, and how those acts were in furtherance of the scheme.

536. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers, prescribers, regulators, and Plaintiff. The RICO Marketing Defendants, Front Groups, and KOLs intentionally crafted the scheme in accordance with the common purpose of the Opioid Marketing Enterprise to ensure that their own profits—and the rewards of the scheme meted out to the Front Groups and KOLs—remained high. In designing and implementing the scheme, the RICO Marketing Defendants understood and intended that those in the distribution chain would rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and scientific evidence regarding the RICO Marketing Defendants' products.

537. The racketeering activities conducted by the RICO Marketing Defendants, Front Groups, and KOLs amounted to a common course of conduct, with a similar pattern and purpose, intended to deceive consumers, prescribers, regulators, and Plaintiff. Each separate use of the U.S. Mail and/or interstate wire facilities employed by the RICO Marketing Defendants was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including consumers, prescribers, regulators and Plaintiff. The RICO Marketing Defendants have engaged in the pattern of racketeering activity for the purpose of conducting the ongoing affairs of the Opioid Marketing Enterprise.

538. Each of the RICO Marketing Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

539. As described herein, the RICO Marketing Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant money and revenue from the marketing and sale of their highly addictive and dangerous drugs.

540. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

541. The RICO Marketing Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff injury in its business and property. They also directly and proximately caused injury to Plaintiff's residents. The RICO Marketing Defendants' pattern of racketeering activity logically, substantially, and foreseeably caused an opioid epidemic. Plaintiff's injuries were not unexpected, unforeseen, or independent. Rather, as Plaintiff alleges, the RICO Marketing Defendants knew that the opioids were unsuited to treatment of long-term chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse. Nevertheless, the RICO Marketing Defendants engaged in a scheme that utilized the mail and interstate wires in order to carry out the Opioid Marketing Enterprises' fraudulent scheme, thereby increasing sales of their opioid products.

542. The RICO Marketing Defendants' creation of, and then participation in, the Opioid Marketing Enterprise through a pattern of racketeering activities to carry-out

their fraudulent scheme has injured Plaintiff in the form of substantial losses of money and property that logically, directly and foreseeably arise from the opioid-addiction epidemic. Plaintiff's injuries, as alleged throughout this Complaint, and expressly incorporated herein by reference, include, *inter alia*, the costs of (a) medical and therapeutic care, and other treatment costs for patients suffering from opioid addiction or disease, overdose, or death; (b) opioid prescriptions for chronic pain paid directly through the Tribe's healthcare program, dispensed as a direct result of Defendants' widespread, pervasive and misleading opioid marketing campaign; (c) increased costs to the Tribe's healthcare program for payment of opioid abuse treatment; (d) counseling, treatment and rehabilitation services; (e) treatment of infants born with opioid-related medical conditions; (f) welfare and foster care for children whose parents suffer from opioid-related disability or incapacitation, including costs of related legal proceedings; (g) law enforcement and public safety connected to the opioid epidemic within the Tribe's community; (h) increased burden on the Tribe's judicial system; (i) re-education of doctors and patients about the appropriate use of opioids; and (j) extensive clean-up of public parks, spaces, and facilities.

543. Plaintiff has also suffered substantial damages in the form of lost casino revenue, lost productivity of tribal members, lost economic activity, lost reputation and good will, and lost opportunity for growth and self-determination. These damages have been suffered and continue to be suffered directly by the Tribe.

544. These damages logically, directly, and foreseeably arose from the opioid-addiction epidemic. The health and welfare of Plaintiff's citizens also have been injured.

545. Plaintiff is most directly harmed and there is no other plaintiff better suited to seek a remedy for the economic harms at issue here.

546. Plaintiff's injuries, as alleged throughout this Complaint, are expressly incorporated herein by reference. Plaintiff seeks all legal and equitable relief as allowed by law, including, *inter alia*, abatement, compensatory damages, punitive damages, attorney fees and costs, as well as pre- and post-judgment interest.

COUNT IV: RACKETEER-INFLUENCED AND CORRUPT ORGANIZATIONS ACT, 18 U.S.C. § 1961 Et Seq. – Opioid Supply Chain Enterprise (Against AmerisourceBergen, Cardinal, McKesson, Purdue, Actavis, Cephalon, Teva, Endo, And Mallinckrodt – "Rico Supply Chain Defendants")

547. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

548. At all relevant times, the RICO Supply Chain Defendants were and are "persons" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

549. The RICO Supply Chain Defendants together formed an association-in-fact enterprise, the Opioid Supply Chain Enterprise, for the purpose of coordination and increasing the quota for and profiting from the increased volume of opioid sales in the United States, including but not limited to, creating a market for non-medical use of opioids of epidemic proportions. The Opioid Supply Chain Enterprise is an association-in-fact enterprise within the meaning of § 1961. The Opioid Supply Chain Enterprise consists of the RICO Supply Chain Defendants. The activities of the Opioid Supply Chain Enterprise affect interstate commerce.

550. Many of the RICO Supply Chain Defendants are members, participants, and/or sponsors of the HDA, and have been since at least 2006, and utilized the HDA to form the interpersonal relationships of the Opioid Supply Chain Enterprise and to assist the RICO Supply Chain Defendants in engaging in the pattern of racketeering activity that gives rise to this Count.

551. At all relevant times, the Opioid Supply Chain Enterprise: (a) had an existence separate and distinct from each of the RICO Supply Chain Defendants; (b) was separate and distinct from the pattern of racketeering in which the RICO Supply Chain Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the RICO Supply Chain Defendants; (d) was characterized by interpersonal relationships among the RICO Supply Chain Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit. Each member of the Opioid Supply Chain Enterprise participated in the conduct of the enterprise through a pattern of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid quotas and resulting sales.

552. The RICO Supply Chain Defendants carried out, or attempted to carry out, a coordinated scheme to defraud federal and state regulators, the American public, and Plaintiff by knowingly conducting or participating in the conduct of the Opioid Supply Chain Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and wire interstate facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud). In so doing, each of the RICO Supply Chain Defendants knowingly conducted and participated in the conduct of the

Opioid Supply Chain Enterprise by engaging in mail and wire fraud in violation of 18 U.S.C. § 1962(c) and (d).

553. The RICO Supply Chain Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e. violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Supply Chain Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity and/or constituted continuous racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the RICO Supply Chain Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Supply Chain Enterprise. The RICO Supply Chain Defendants participated in the scheme to defraud by using mail, telephone and the Internet to transmit mailings and wires in interstate or foreign commerce.

554. The RICO Supply Chain Defendants also conducted and participated in the conduct of the affairs of the Opioid Supply Chain Enterprise through a pattern of racketeering activity by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

555. The RICO Supply Chain Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 843(a)(4) makes it unlawful for any person knowingly or intentionally to furnish false or

fraudulent information in, or omit any material information from, any application, report, record or other document required to be made, kept or filed under this subchapter. A violation of § 843(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 843(d)(1).

556. In sum, the RICO Supply Chain Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) consisted of:

a. Mail Fraud: The RICO Supply Chain Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, false promises, and omissions.

b. Wire Fraud: The RICO Supply Chain Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by interstate wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, false promises, and omissions.

c. Controlled Substance Violations: The RICO Supply Chain Defendants who are Distributor RICO Supply Chain Defendants violated 21 U.S.C. § 843 by knowingly or intentionally furnishing false or fraudulent information in, and/or omitting material information from, documents filed with the DEA.

557. The RICO Supply Chain Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

558. The RICO Supply Chain Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

559. The RICO Supply Chain Defendants hid from the general public and suppressed and/or ignored warnings from third parties, whistleblowers, and governmental entities about the reality of the suspicious orders that the RICO Supply Chain Defendants were filling on a daily basis – leading to the diversion of hundreds of millions of doses of prescription opioids into the illicit market.

560. The RICO Supply Chain Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in a coordinated, common course of conduct to commit acts of fraud.

561. Indeed, for the RICO Supply Chain Defendants' fraudulent scheme to work, each of the RICO Supply Chain Defendants had to agree to implement similar tactics.

562. As described herein, the RICO Supply Chain Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

563. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiff's business and property, as well as the health and welfare of Plaintiff's citizens, while simultaneously generating billion-dollar revenue and profits for the RICO Supply Chain Defendants. The predicate acts were committed or caused to be committed by the RICO Supply Chain Defendants through their participation in the Opioid Supply Chain Enterprise and in furtherance of its fraudulent scheme.

564. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

565. Many of the precise dates of the RICO Supply Chain Defendants' criminal actions at issue here have been hidden by RICO Supply Chain Defendants and cannot be alleged without access to RICO Supply Chain Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Supply Chain Enterprise alleged herein depended upon secrecy.

566. By intentionally refusing to report and halt suspicious orders of their prescription opioids, RICO Supply Chain Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

567. It was foreseeable to the RICO Supply Chain Defendants that Plaintiff would be harmed when they refused to report and halt suspicious orders, because their violation of the duties imposed by the CSA and Code of Federal Regulations allowed the widespread diversion of prescription opioids out of appropriate medical channels and into the illicit drug market—causing the opioid epidemic that the CSA intended to prevent.

568. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

569. The RICO Supply Chain Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff's injury in its business and property. The RICO Supply Chain Defendants' pattern of racketeering activity, including their refusal to identify, report and halt suspicious orders of controlled substances, logically, substantially, and foreseeably caused an opioid epidemic. Plaintiff

was injured by the RICO Supply Chain Defendants' pattern of racketeering activity and the opioid epidemic that it created.

570. RICO Supply Chain Defendants knew that the opioids they manufactured and supplied were unsuited to treatment of long-term, chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse. Nevertheless, in order to increase sales of their opioid products, the RICO Supply Chain Defendants engaged in a scheme of deception by refusing to identify or report suspicious orders of prescription opioids that they knew were highly addictive, subject to abuse, and were actually being diverted into the market of non-medical use. They did so by utilizing the mail and interstate wires as part of their fraud.

571. The RICO Supply Chain Defendants' predicate acts and pattern of racketeering activity were a proximate cause of the opioid epidemic that has injured Plaintiff in the form of substantial losses of money and property that logically, directly, and foreseeably arise from the opioid-addiction epidemic brought on by the RICO Supply Chain Defendants' acts. The RICO Supply Chain Defendants' predicate acts also injured the health and welfare of Plaintiff's residents.

572. Plaintiff's injuries, as alleged throughout this Complaint, and expressly incorporated herein by reference, include, *inter alia*, the costs of (a) medical and therapeutic care, and other treatment costs for patients suffering from opioid addiction or disease, overdose, or death; (b) opioid prescriptions for chronic pain paid directly through the Tribe's healthcare program, dispensed as a direct result of Defendants' widespread, pervasive and misleading opioid marketing campaign; (c) increased costs to Tribe's

healthcare program for payment of opioid abuse treatment; (d) counseling, treatment and rehabilitation services; (e) treatment of infants born with opioid-related medical conditions; (f) welfare and foster care for children whose parents suffer from opioid-related disability or incapacitation, including costs of related legal proceedings; (g) law enforcement and public safety connected to the opioid epidemic within the Tribe's community; (h) increased burden on the Tribe's judicial system; (i) re-education of doctors and patients about the appropriate use of opioids; and (j) extensive clean-up of public parks, spaces, and facilities.

573. The predicate acts and pattern of racketeering activity proximately caused Plaintiff's injuries, as alleged throughout this Complaint, including Count III of this Complaint, and such allegations are expressly incorporated herein by reference.

574. Plaintiff's injuries, as alleged throughout this Complaint, are hereby expressly incorporated herein by reference.

575. Plaintiff is most directly harmed and there is no other plaintiff better suited to seek a remedy for the economic harms at issue here.

576. Plaintiff's injuries, as alleged throughout this Complaint, are expressly incorporated herein by reference. Plaintiff seeks all legal and equitable relief as allowed by law, including, *inter alia*, abatement, compensatory damages, punitive damages, attorney fees and costs, as well as pre- and post-judgment interest.

COUNT V: LANHAM ACT, 15 U.S.C. § 1125(a)(1)(B)

Against All Defendants

577. Plaintiff realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

578. The Lanham Act, 15 U.S.C. § 1125(a), provides, in pertinent part:

> (1) Any person who, on or in connection with any goods or services . . . uses in commerce any . . . false or misleading description of fact, or false or misleading representation of fact, which –
>
> (B) in commercial advertising or promotion, misrepresents the nature, characteristics [or] qualities . . . of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

579. As alleged herein, Defendants, in connection with their manufacture, distribution, and/or sale of prescription opioids, made numerous false or misleading descriptions and representations of fact during the advertising and promotion of prescription opioids.

580. These false or misleading descriptions and representations of fact misrepresented the nature, characteristics, or qualities of the prescription opioids.

581. As described herein, Manufacturer Defendants misrepresented the safety and efficacy of prescription opioids. Diversion Defendants misleadingly represented that they were taking effective steps to prevent diversion.

582. Defendants' misrepresentations proximately caused Plaintiff's injuries, as alleged throughout this Complaint, and such allegations are expressly incorporated herein by reference.

583. Plaintiff's injuries, as alleged throughout this Complaint, are expressly incorporated herein by reference. Plaintiff seeks all legal and equitable relief as allowed by law, including, *inter alia*, abatement, compensatory damages, punitive damages, attorney fees and costs, as well as pre- and post-judgment interest.

COUNT VI: INTENTIONAL MISREPRESENTATION

Against All Defendants

584. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein.

585. The Defendants made fraudulent misrepresentations and omissions of material fact. Defendants' knowing deceptions during the relevant period, more fully described in this Complaint, were intended to induce reliance.

586. Those misrepresentations and omissions were known to be untrue by the Defendants, or were recklessly made.

587. As alleged herein, the Manufacturer Defendants engaged in false representations and concealments of material fact regarding the use of name-brand and generic opioids to treat chronic non-cancer pain.

588. As alleged herein, Defendants made false statements and/or omissions regarding their compliance with state and federal law regarding their duties to prevent diversion, their duties to monitor, report and halt suspicious orders, and/or concealed their noncompliance with these requirements. Defendants also failed to disclose the prevalence of diversion of controlled substances, including opioids within the Tribe's community.

589. The Defendants made those misrepresentations and omissions in an intentional effort to deceive Plaintiff and Plaintiff's community, despite the Defendants' knowledge of the dangers of such use of name-brand and generic prescription opioids.

590. In addition, and independently, Marketing Defendants had a duty not to deceive Plaintiff because Defendants had in their possession unique material knowledge that was unknown, and not knowable, to Plaintiff, Plaintiff's agents, physicians, and the public.

591. The Defendants continued making those misrepresentations, and failed to correct those material omissions, despite repeated regulatory settlements and publications demonstrating the false and misleading nature of the Defendants' omissions and/or claims.

592. Defendants had a duty to disclose the above-referenced material facts, yet concealed them. These false representations and concealed facts were material to the conduct and actions at issue. Defendants made these false representations and concealed facts with knowledge of the falsity of their representations and did so with the intent of misleading Plaintiff, Plaintiff's community, the public, and persons on whom these entities relied.

593. Defendants intended and had reason to expect under the operative circumstances that Plaintiff, Plaintiff's agents, physicians, the public, and persons on whom Plaintiff and its agents relied would be deceived by Defendants' statements, concealments, and conduct as alleged herein and that these entities would act or fail to act in reasonable reliance thereon.

594. Plaintiff, Plaintiff's community, and others, did in fact rightfully, reasonably, and justifiably rely on Defendants' representations and/or concealments, both directly and indirectly.

595. For instance, doctors, including those serving the Tribe and its members, relied on the Defendants' misrepresentations and omissions in prescribing opioids for chronic pain relief. Patients, including members of the Tribe, relied on the Defendants' misrepresentations and omissions in taking prescription opioids for chronic pain relief.

596. Also, as a result of these representations and/or omissions, Plaintiff proceeded under the misapprehension that the opioid crisis was simply a result of conduct by persons other than Defendants. As a consequence, these Defendants prevented Plaintiff from a more timely and effective response to the opioid crisis.

597. Defendants' misconduct alleged in this case is ongoing and persistent.

598. Plaintiff's community has experienced an unprecedented opioid addiction and overdose epidemic leading to increased costs for, *inter alia*, treatment services, autopsies, emergency room visits, medical care, treatment for related illnesses and accidents, payments for fraudulent or medically unnecessary prescriptions, and lost productivity to the Tribe's workforce.

599. As a direct and foreseeable consequence of Defendants' fraud, Plaintiff has incurred and continues to incur costs for opioid prescriptions in excess of those Plaintiff would have otherwise incurred.

600. The injuries alleged by Plaintiff herein were sustained as a direct and proximate result of Defendants' fraudulent conduct.

601. Plaintiff's injuries, as alleged throughout this Complaint, are expressly incorporated herein by reference. Plaintiff seeks all legal and equitable relief as allowed by law, including, *inter alia,* abatement, compensatory damages, punitive damages, attorney fees and costs, as well as pre- and post-judgment interest.

COUNT VII: NEGLIGENCE AND GROSS NEGLIGENCE

Against All Defendants

602. Plaintiff realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

603. To establish actionable negligence in Idaho, Plaintiff must show a duty, a breach of that duty, and injury resulting proximately therefrom.

604. Defendants have a duty to exercise reasonable care under the circumstances, in light of the risks. This includes a duty not to cause foreseeable harm to others. In addition, these Defendants, having engaged in conduct that created an unreasonable risk of harm to others, had, and still have, a duty to exercise reasonable care to prevent the threatened harm.

605. In addition, Defendants had a duty not to breach the standard of care established under Idaho law and the federal Controlled Substances Act ("CSA") and it's implementing regulations, which require Defendants to report suspicious orders and to maintain systems to detect and report such activity.

606. Defendants voluntarily undertook a legal duty to prevent the diversion of prescription opioids by engaging in the distribution of prescription opioids and by making public promises to prevent the diversion of prescription opioids.

607. Defendants knew of the serious problem posed by prescription opioid diversion and were under a legal obligation to take reasonable steps to prevent diversion.

608. Defendants knew of the highly addictive nature of prescription opioids and of the high likelihood of foreseeable harm to patients and communities, including the Tribe, from prescription opioid diversion.

609. As described throughout the Complaint, in language expressly incorporated herein, Defendants breached their duties to exercise due care in the business of wholesale distribution of dangerous opioids, which are Schedule II Controlled

Substances, by failing to monitor for, failing to report, and filling highly suspicious orders time and again.

610. As described throughout the Complaint, in language expressly incorporated herein, Defendants misrepresented their compliance with their duties under the law and concealed their noncompliance and shipments of suspicious orders of opioids to Plaintiff's community and destinations from which they knew opioids were likely to be diverted into Plaintiff's community, in addition to other misrepresentations alleged and incorporated herein.

611. The Manufacturer Defendants breached their duty to Plaintiff by deceptively marketing and sale of name-brand and generic opioids, including minimizing the risks of addiction and overdose and exaggerating the purported benefits of long-term use of opioids for the treatment of chronic pain and failing to take the necessary steps to adequately inform doctors, healthcare providers and the medical community of the proper use and the abuse and addiction risks associated with their name-brand and generic opioid products in accordance with their product labels.

612. Manufacturer Defendants knew or should have known, that their affirmative misconduct in engaging in an aggressive, widespread, and misleading campaign in marketing narcotic drugs and their failure to inform doctors and the medical community of the proper use and risks associated with their products created an unreasonable risk of harm. The Defendants' sales data, reports from sales representatives, and internal documents, should have put them on notice that such harm was not only foreseeable, but was actually occurring. Defendants nevertheless chose to deceptively

withhold information about the dangers of opioids from Plaintiff, physicians, patients, and the public.

613. Defendants' breaches were intentional and/or unlawful, and Defendants' conduct was willful, wanton, malicious, reckless, oppressive, and/or fraudulent.

614. Defendants' misconduct alleged in this case is ongoing and persistent.

615. Defendants acted with actual malice in breaching their duties, i.e., they have acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

616. As is described throughout this Complaint, Defendants acted without even slight diligence or scant care, and with indifference, and were negligent in a very high degree, disregarding the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

617. Plaintiff is not asserting a cause of action under the CSA or other controlled substances laws cited above. Rather, it seeks to remedy harms caused to it by the breach of duty defined by these statutes and under common law.

618. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered and will continue to suffer economic damages including, but not limited to, significant expenses for police, emergency, health, prosecution, and rehabilitation services as well as lost casino revenue and the cost of opioid prescriptions and addiction treatment paid through the Tribe's healthcare program.

619. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered and will continue to suffer stigma damage, non-physical property damage, and damage to its proprietary interests.

620. Defendants' breaches of their duty of care foreseeably and proximately caused damage to the Tribe and its members.

621. Plaintiff's injuries, as alleged throughout this Complaint, are expressly incorporated herein by reference. Plaintiff seeks all legal and equitable relief as allowed by law, including, *inter alia*, abatement, compensatory damages, punitive damages, attorney fees and costs, as well as pre- and post-judgment interest.

COUNT VIII: NEGLIGENCE PER SE

Against All Defendants

622. The Tribe incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further allege as follows.

623. All Defendants were obligated to prevent the diversion of prescription opioids under the CSA and its implementing regulations.

624. The CSA and its implementing regulations were enacted to promote safety and to prevent exactly the type of harm that occurred as a result of Defendants' failures.

625. All Defendants failed to perform their statutory and regulatory obligations under the CSA.

626. Idaho law requires the design and operation of a system to detect and disclose suspicious orders of controlled substances pursuant to Idaho Code § 37-2720.

627. Idaho Code § 37-2720 was enacted to promote safety and prevent the type of harm that occurred as a result of Defendants' failures.

628. All Defendants engaged in misrepresentation and fraud, and aided and abetted the use of misrepresentation and fraud, in the distribution of prescription opioids in Idaho.

629. Defendants' breaches of their duty of care foreseeably and proximately caused damage to the Tribe and its members.

630. The Tribe is entitled to damages from Defendants in an amount to be determined in this litigation.

COUNT IX: UNJUST ENRICHMENT

Against All Defendants

631. The Tribe incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein.

632. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from the increase in the distribution and purchase of their name-brand and generic opioid products within Plaintiff's community, including from opioids foreseeably and deliberately diverted within and into Plaintiff's community.

633. Plaintiff has expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Defendants' conduct.

634. These expenditures include, but are not limited to, the provision of healthcare services and treatment services to people who use opioids. Plaintiff has also incurred expenses for opioid prescriptions for chronic pain paid directly through the Tribe's healthcare program, dispensed as a direct result of Defendants' widespread, pervasive and misleading opioid marketing campaign. Plaintiff has also made payments through its healthcare program for opioid addiction treatment.

635. These expenditures have helped sustain Defendants' businesses.

636. Plaintiff has conferred a benefit upon Defendants by paying for Defendants' externalities: the cost of the harms caused by Defendants' improper distribution practices.

637. Defendants were aware of these obvious benefits, and their retention of the benefit is unjust.

638. Plaintiff has paid for the cost of Defendants' externalities and Defendants have benefited from those payments because they allowed them to continue providing customers with a high volume of opioid products. Because of their deceptive marketing of prescription opioids, Marketing Defendants obtained enrichment they would not otherwise have obtained. Because of their conscious failure to exercise due diligence in preventing diversion, Defendants obtained enrichment they would not otherwise have obtained. The enrichment was without justification and Plaintiff lacks a remedy provided by law.

639. Defendants have unjustly retained benefits to the detriment of Plaintiff, and Defendants' retention of such benefits violates the fundamental principles of justice, equity, and good conscience.

640. Defendants' misconduct alleged in this case is ongoing and persistent.

641. Plaintiff's injuries, as alleged throughout this Complaint, are expressly incorporated herein by reference. Plaintiff seeks all legal and equitable relief as allowed by law, including, *inter alia*, abatement, compensatory damages, punitive damages, attorney fees and costs, as well as pre- and post-judgment interest.

COUNT X: CIVIL CONSPIRACY

Against All Defendants

642. Plaintiff realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

643. Defendants engaged in a civil conspiracy in their unlawful marketing and sale of opioids and/or distribution of name-brand and generic opioids into Idaho and Plaintiff's community.

644. Defendants engaged in a civil conspiracy to commit fraud and misrepresentation in conjunction with their unlawful marketing and sale of opioids and/or distribution of opioids into Idaho and Plaintiff's community.

645. Defendants unlawfully failed to act to prevent diversion and failed to monitor for, report, and prevent suspicious orders of opioids.

646. The Marketing Defendants further unlawfully marketed opioids in Idaho and Plaintiff's community in furtherance of that conspiracy.

647. Defendants' conspiracy and acts in furtherance thereof are alleged in detail in this Complaint, including, without limitation, in Plaintiff's Counts for violations of RICO and the Idaho Statutes. Such allegations are specifically incorporated herein.

648. Defendants acted with a common understanding or design to commit unlawful acts, as alleged herein, and acted purposely, without a reasonable or lawful excuse, which directly and proximately caused the injuries alleged herein.

649. Defendants acted with malice, purposely, intentionally, unlawfully, and without a reasonable or lawful excuse.

650. Defendants conduct in furtherance of the conspiracy described herein was not mere parallel conduct because each Defendant acted directly against their commercial interests in not reporting the unlawful distribution practices of their competitors to the

authorities, which they had a legal duty to do. Each Defendant acted against their commercial interests in this regard due to an actual or tacit agreement between the Defendants that they would not report each other to the authorities so they could all continue engaging in their unlawful conduct.

651. Defendants' conspiracy, and Defendants' actions and omissions in furtherance thereof, caused the direct and foreseeable losses alleged herein.

652. Defendants' actions demonstrated both malice and also aggravated and egregious fraud. Defendants engaged in the conduct alleged herein with a conscious disregard for the rights and safety of other persons, even though that conduct has a great probability of causing substantial harm.

653. Defendants' misconduct alleged in this case is ongoing and persistent.

654. Plaintiff's injuries, as alleged throughout this Complaint, are expressly incorporated herein by reference. Plaintiff seeks all legal and equitable relief as allowed by law, including, *inter alia*, abatement, compensatory damages, punitive damages, attorney fees and costs, as well as pre- and post-judgment interest.

COUNT XI: DECEPTIVE TRADE PRACTICES
Idaho Code. § 48-603
Against All Defendants

655. Plaintiff realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

656. Idaho Code § 48-603 prohibits misrepresenting the quality of goods, as well as sales sounding in fraud, misrepresentation, or deceptive practices.

657. As more fully described in this Complaint, Defendants committed repeated and willful, unfair, or deceptive acts or practices, and unconscionable trade

practices, in connection with the sale, marketing and distribution of merchandise and specifically, their name-brand and generic opioid products.

658. Defendants' unfair, deceptive, and unconscionable representations, concealments, and omissions were reasonably calculated to deceive the Tribe, the public, and their agents.

659. As described more specifically above, Defendants' misrepresentations, concealments, and omissions constitute a willful course of conduct which continues to this day.

660. Each Defendant failed to report and/or prevent the diversion of highly addictive prescription drugs. Because of the dangerously addictive nature of these drugs, the Distributor Defendants' manufacturing, marketing, sales, and distribution practices unlawfully caused an opioid and heroin plague and epidemic. Each Defendant had a nondelegable duty to guard against and prevent the diversion of prescription opioids to other than legitimate medical, scientific, and industrial channels.

661. The Defendants also omitted material facts, causing confusion or misunderstanding as to approval or certification of goods or services.

662. The Defendants failed to disclose the material facts that, *inter alia*, they were not in compliance with laws and regulations requiring that they maintain a system to prevent diversion, protect against addiction and severe harm, and specifically monitor, investigate, report, and refuse suspicious orders. But for these material factual omissions, Defendants would not have been able to sell opioids, and the Distributor Defendants would not have been able to receive and renew licenses to sell opioids.

663. As alleged herein, each Manufacturer Defendant wrongfully represented that the opioid prescription medications they manufactured, marketed, and sold had characteristics, uses, or benefits that they do not have.

664. The Manufacturer Defendants also wrongfully misrepresented that the opioids were safe and effective when such representations were untrue, false, and misleading.

665. The Manufacturer Defendants also used exaggeration and/or ambiguity as to material facts and omitted material facts, with an intent deceive.

666. Because of the dangerously addictive nature of these drugs, which the Manufacturer Defendants concealed and misrepresented, they lacked medical value, and in fact caused addiction and overdose deaths; therefore, Defendants' sales and marketing of opioids constituted a violation of state law.

667. The Manufacturer Defendants made deceptive representations about the use of opioids to treat chronic non-cancer pain. Each Manufacturer Defendant also omitted or concealed material facts and failed to correct prior misrepresentations and omissions about the risks and benefits of opioids. Each Defendant's omissions rendered even their seemingly truthful statements about opioids deceptive.

668. All of Distributor and Manufacturer Defendants' actions of fraud, false pretenses, false promises, misrepresentations, misleading statements, and deceptive practices discussed herein, were made with the intent that others, including Plaintiff and Plaintiff's community, rely thereon.

669. The damages which Plaintiff seeks to recover were sustained as a direct and proximate cause of the Manufacturer and Distributor Defendants' intentional actions and omissions.

670. Because of Defendants' omissions and deceptive misrepresentations to, *inter alia*, Plaintiff, its residents, and their agents, Plaintiff has incurred significant damages, including, but not limited to, those alleged throughout this Complaint, which are expressly incorporated herein by reference.

PRAYER FOR RELIEF

WHEREFORE, the Tribe respectfully requests judgment in its favor granting the following relief:

a) Entering Judgment in favor of the Tribe in a final order against each of the Defendants;

b) An award of actual and consequential damages in an amount to be determined at trial;

c) An award of all damages resulting from Defendants' violation of 18 U.S.C. § 1962(c) and (d), including prejudgment interest, the sum trebled pursuant to 18 U.S.C. § 1962(c);

d) An order obligating Defendants to disgorge all revenues and profits derived from their scheme;

e) Ordering that Defendants compensate the Tribe for past and future costs to abate the ongoing public nuisance caused by the opioid epidemic;

f) Ordering Defendants to fund an "abatement fund" for the purposes of abating the public nuisance;

g) Awarding the damages caused by the opioid epidemic, including, *inter alia*, (a) costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (b) costs for providing treatment, counseling, and rehabilitation services; (c) costs for providing treatment of infants born with opioid-related medical conditions; (d) costs for providing care for children whose

parents suffer from opioid-related disability or incapacitation; (e) costs associated with law enforcement and public safety relating to the opioid epidemic; (f) costs for cleanup of public areas; (g) costs for payment of opioids and opioid addiction treatment from the Tribe's healthcare program; (h) lost casino revenue;

h) An award of punitive damages;

i) Injunctive relief prohibiting Defendants from continuing their wrongful conduct;

j) An award of the Tribe's costs, including reasonable attorney's fees, pursuant to 18 U.S.C. § 1964(c);

k) Pre- and post-judgment interest as allowed by law; and

l) Any other relief deemed just, proper, and/or equitable.

PLAINTIFF DEMANDS A JURY TRIAL ON ALL CLAIMS SO TRIABLE

Dated: June 6, 2019

Skikos, Crawford, Skikos & Joseph LLP

By: */s/ Steven Skikos*

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